労災疾病臨床研究事業費補助金

職場における腰痛の効果的な治療法等に関する研究

平成28年度　総括・分担研究報告書

主任研究者　松平　浩

平成29年3月

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Ⅰ. 総括研究報告

労災疾病臨床研究事業費補助金

平成 28 年度総括研究報告書

職場における腰痛の効果的な治療法等に関する研究

研究代表者　松平浩　東京大学医学部附属病院 22 世紀医療センター
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研究要旨

本研究では、世界的にみてもいまだ克服されていない腰痛対策をテーマに、特に介護看護従事労働者をターゲットとして、疫学的手法を用いたリスク因子の同定、発症予防に役立つ体操や福祉機器および両立支援手法の開発ついての取り組みを、3 年計画で包括的に推進した。最終年度の検討結果は以下の通りである。

1)作業支障腰痛が遷延するリスクとして、職場を主とする心理社会的要因が大きく関与することが明らかになった。
2)開発した福祉機器装着（歩行時）時の高次運動野の活動への影響を近赤外光脳機能計測装置により検討した結果、装具の着用で垂直姿勢の維持や運動制御に関わる高次運動野の活動が修飾されることが明らかになった。
3)姿勢と腰部負担との関連を、三次元動作分析装置を用いて明らかにした。適度な骨盤前傾と体幹伸展の姿勢では腰部負担が小さくなることがわかったため、この姿勢をとることをフィードバックする新たな福祉機器「不良姿勢チェッカー」を作製し、その有用性を確認した。
4) 腰痛スクリーニングに活用可能な腰椎 MRI 画像診断アルゴリズムを構築した。
5)簡易で即実践できる体操に加え、産業理学療法士からの科学的根拠に基づいた腰痛教育の有益性を、全国の 12 労災病院をクラスターとして大規模介入比較試験を行い検証した。ベースライン調査では 4,767 名にアンケートを配布、アンケート回収数は 3,439 名、解析には 3,381 名分のアンケートを利用した。6 か月後の追跡調査時の、各群の回収数は 2,406 名であり、追跡率は 70.0%あった。、腰痛の自覚症状改善の割合は,コントロール群に比して、腰椎伸展体操の普及・実践群、+産業理学療法士による腰痛教育・相談いずれの介入によっても上昇していた。多変量を調整した Logistic 回帰分析の結果、両介入群とも有意に腰痛を改善（コントロール群の約 2 倍）することが分かった。
6)産業理学療法士によるメール指導は、相談者の腰痛予防のための行動変容を促すのに効果的であり、両立支援手法の一手段となる可能性があると思われた。

最終的な本研究グループの活動成果として効率的かつ包括的な作業関連性腰痛の予防対策の提言を作成した。同提言は、社会・医療経済面、更には労災補償面にも大きく貢献するものと考えている。

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A. 研究目的

厚生労働省が公表する「国民生活基礎調査の概要」において, 国民の代表的愁訴（有訴者率）が, 腰痛（男 1 位, 女 2 位）, 肩こり（男 2 位, 女 1 位）であることはよく知られているが、同じく厚生労働省が公表する業務上疾病発生状況等調査によると、休業 4 日以上の業務上疾病の発生件数のうち腰痛は、長年に渡り全職業性疾病の約 6 割を占め第 1 位である。平成 23 年の腰痛全届け出のうち社会福祉施設が 19%を占め、10 年で 2.7 倍という最も顕著な増加となった背景を踏まえ、19 年ぶりに改訂された「職場における腰痛予防対策指針」（平成 25 年、厚生労働省）では、重症心身障害児施設等に限定されていた適用を、福祉・医療等における介護・看護作業全般に拡大し、内容を充実させるに至った。つまり、介護・看護従事者への腰痛対策は、産業衛生領域の喫緊の課題といえる。また世界疾病負担研究にて 289 の疾患や傷病のうち、腰痛が Years Lived with Disability (YLDs)、つまり健康でない状態で生活する年数を指標とする統計のトップにランクされるなど、社会的損失や健康面への影響の大きい腰痛への対策はグローバルにも重要な課題として位置づけられている。

研究代表者は、昨年度まで行われた「労災疾病等 13 分野研究」の本分野において世界標準のエビデンスを踏まえつつ独創的な研究を展開し、近年、国際的にも評価される業績を公表してきた（13 分野研究の総括事後評価点数：5 点満点で 4.9)。

本研究では、世界的にみてもいまだ克服されていない腰痛対策に関し、臨床専門の医師のみならず産業医学・産業保健、看護、人間工学、福祉工学、統計学といった様々な分野のスペシャリストを分担研究者、研究協力者として多数招聘し、これまでの主任研究者の実績と研究基盤をさらに

発展させる。特に介護看護従事労働者をターゲットとして、疫学的手法を用いたリスク因子の同定、発症予防を目的とした介入法の構築、福祉用具の開発や利用および職業と治療の両立支援法の作成を、PDCA サイクルも有効に活用しつつ包括的に推進することとした。

具体的には、3年計画で以下のサブテーマに基づき遂行する予定とした。①腰痛に関わる実態およびリスクの同定、②予防に有用な福祉機器等の開発、③介護看護従事者への予防介入法とマネジメントシステムの構築、④個人と職場の双方に有益な腰痛治療と職業生活との両立支援手法の開発、以上を踏まえた⑤労働安全衛生マネジメントシステム構築を視野に入れた提言作成。

3 年間推進した研究に関し、上①～⑤のサブテーマ毎に報告する。なお研究代表者である松平と分担研究者の岡は全ての分担研究に参画し、研究デザイン・統計解析を行っている。

B. 研究方法

① 腰痛に関わる実態およびリスクの同定

1. 単一医療介護施設の職員を対象に、自記式調査票を用いた横断研究において、腰痛の現状およびその関連因子について心理社会的要因を中心に探索した。対象は、某医療法人社団の職員 280 名とし、無記名の自記式質問票を郵送にて回収した。
2. 心身の健康に関するインターネット調査にて労働力人口として現役世代である 20-64 歳の慢性腰痛のを持つ 20-64 歳の日本人約 3,000 人を対象に健康関連 QOL と身体化，抑うつ症状の関連を評価した.解析では抑うつ，年齢，性別，BMI，喫煙，婚姻，学歴，定期的な運動，雇用状況，通院していた疾患の個数（0－25）を調整した.

②予防に有用な福祉機器等の開発

1. 腰部負担の大きい重量物挙上における持ち上げ姿勢と，負担は小さくとも蓄積されると腰痛の発症につながると考え，立位姿勢も対象として良姿勢が腰部負担に与える影響を三次元動作分析装置を用いて明らかにした.適度な骨盤前傾と体幹伸展の姿勢では腰部負担が小さくなることがわかったため，この姿勢をとることをフィードバックする「不良姿勢チェッカー」を作製した.
2. 腰椎の画像所見と腰痛とが必ずしも一致しない症例が、臨床的には散見される。なかでも腰椎 MRI は空間分解能も高く、優れたモダリティであるが労働者における疫学的な検討は不十分である。、関東労災病院に勤務する職員にて画像データベースを構築し腰椎 MRI 所見と過去の高度な腰痛の既往との関連を分析した。
3. 従来の体幹装具は装着することで体幹運動を制限することで腰部負担の軽減を目指している。しかしながら、先行研究では体幹装具装着による腰部負担の軽減効果を示すことができていない。また、体幹装具は長期間装着すると体幹周囲筋、特に側腹筋の弱化につながると指摘されている。そこで継手の抗力により胸部を前方から押す力を与えることで腹筋の活動を促通し、背筋の活動を低減する新たなコンセプトの体幹装具 Trunk solution（以下 TS）を開発し、2014 年の Good Design 賞を受賞した。本年度は、開発した TS 装着（歩行時）時の高次運動野の活動への影響を、8 名の被験者にて近赤外光脳機能計測装置により検討した。

③介護看護従事者への予防介入法とマネジメントシステムの構築

主任研究者は、勤務中多忙な介護看護従事者が簡易で即実践できる腰痛予防体操（腰を反らす“これだけ体操”）を、ポピュレーションアプローチとして実践することにより職場の腰痛状況を改善できる可能性を先行研究で示している。本研究では、産業衛生領域の喫緊の課題

である腰痛予防対策を効率的に行うマネジメントシステムを構築する基盤として、簡易で即実践できる体操に加え、産業理学療法士からの科学的根拠に基づいた腰痛教育の有益性を、大規模介入比較試験により検証した。全国の 12 労災病院をクラスターとして、A:対照（無介入）、B：腰椎伸展体操の普及・実践、C:B+産業理学療法士による腰痛教育・相談の実践の 3 群を実施する臨床研究を実施した。

- 施設をクラスターとした無作為比較試験
- 対照（無介入）、腰椎伸展体操の普及・実践、B の介入+産業理学療法士による腰痛教育・相談の実践の 3 群
- 北海道中央（予定看護師数:155）、東北（421）、関東（610）、横浜（585）、新潟（261）、浜松（236）、旭（189）、大阪（662）、関西（619）、中国（363）、愛媛（180）、長崎（300）、総計 4,581 名をリクルート。以上 12 労災病院（施設）のをクラスターとし、病床・看護師数、看護師の男女数・平均年齢を割付調整因子とし、コンピューターの乱数表を用い、3 群（4 施設ごと）に無作為割付する非盲検試験
- エンドポイント：腰痛の有無および仕事への支障度を勘案した腰痛 grade（重症度）の改善
- 介入期間：1 年
- 選択基準:選定された労災病院に勤務する成人（20 歳以上）看護師、本研究の趣旨に賛同し同意を得た者。
- 除外基準：妊婦，あるいは妊娠の疑いがある場合、腰椎伸展により症状が誘発される腰部脊柱管狭窄症と診断されたことがある者、研究の同意を撤回した者。

<u>④個人と職場の双方に有益な腰痛治療と職業生活との両立支援手法の開発</u>

業務上疾病の約 6 割を占める腰痛には、人間工学的要因のみならず心理社会的要因も関与することが科学的根拠のある事項として認識され、さらには正しい情報の提供や周囲の励ます態度などは腰痛を軽快させることが明らかになりつつある。

一方、腰痛予防に関しても、特定健診・保健指導で用いられるメール指導による腰痛予防効果の有効性が期待されたため、両立支援手法の一手段として産業理学療法士主導で取り組んできた。その結果、メール指導前後において労働者が各自の職務をどれほど上手にできているかを表す指標である Work Ability Index（WAI）の有意な向上、腰痛に関わる就労状況を含めた予後規定因子としてグローバルに最も重要視されている恐怖回避の思考・行動を表す Fear-Avoidance Beliefs Questionnaire（FABQ）の改善傾向を認め、産業理学療法士による腰痛予防を主軸とする両立支援を目的としたメール指導の一定の効果を確認してきた。

本研究では多数の労働者を対象としてメール指導ができるように独自のシステムを開発した．また，世界における労働者を対象とした理学療法（産業理学療法）の介入やその教育課程に関して情報収集を行った．さらに，腰痛予防教育教材を開発した．専用のシステムは，産業理学療法指導システム「Consulting system for physical therapy in occupational health: Compo」と命名した．

開発したシステムを用いて，保健衛生業に従事する労働者を対象として，メール指導による腰痛予防効果を検証した．また，世界の産業理学療法の情報収集を継続した．さらに，開発した腰痛予防教育教材の普及を行った．

Compo を用いた介入研究は，臨床試験登録システム UMIN-CTR（UMIN000018450）に登録した．30 歳から 65 歳までの保健衛生業に従事する者を対象として，Compo を用いて指導を行う群（介入群）と介入を行わない群（対照群）の 2 群に振り分け，研究を実施した．

研究手順として，国内の 11 施設の協力を得た．介入・観察期間は 6 カ月である．まず，指導者から対象者へメールを送信し，以降，1 カ月に 1 回，指導者から対象者へメールを送信することを原則とした（計 7 回）．

⑤労働安全衛生マネジメントシステム構築を視野に入れた提言作成

上述した全ての研究より得られた知見から研究代表者が、多くの施設で導入可能な簡易な「マネジメントシステムを視野に入れた提言」を作成した。

（倫理面への配慮）

独立行政法人労働者健康福祉機および関連各労災病院、国際医療福祉大学、関西福祉科学大学、東京大学医学部附属病院の倫理審査の承認を得ている．被験者に対してはデータを ID 化して管理するなど個人情報には十分配慮している。

C. 研究結果

① 腰痛に関わる実態およびリスクの同定

1. アンケートの有効回答者数 203 名（72.5%）であった。平均年齢は 39.8 歳（SD 12.2)、性別は 70%が女性であった。対象者のうち、仕事に支障をきたした腰痛経験者は 36 名（17.7%）であった。上記腰痛経験者の群とそれ以外の群で、各調査項目について群間比較を行ったところ、FABQ（恐怖回避思考、p = 0.037)、SSS-8（身体症状、p = 0.0003)、職場での対人関係ストレス（p = 0.022）が統計学的な有意差を認めた。年齢、性別、BMI、職業を調整したロジスティック解析においても、上記 3 要因が有意な因子として抽出された。
2. 参加者は平均 44.5±11.2 歳で，48%が女性であった．PHQ-2 は 1576 人(51%) が 0,632 人(20%)が 1,892 人（29%)が 2 であった．EQ-5D は平均 0.78±0.18 であり， PHQ-2 の点数が高くなるほど低かった． SSS-8 の平均スコアは 9.67±6.68 で，PHQ-2 の点数が高くなるほど，SSS-8 が非常に高い（≥16）の割合が高かった．SSS-8 と PHQ-2 の交互作用は統計的に優位でなかったので，最終モデルには含めなかった．最終的な多変量モデルでは，年齢，性別，BMI，喫煙，婚姻，学歴（短大以上か)，定期的な運動の有無，雇用状況（正規雇用かそれ以外か)，通院していた疾患の個数（0－25）を調整した．PHQ-2 の点数は EQ-5D のスコアと有意に関連していた．SSS-8 のどのカテゴリに属するかは，PHQ-2 の点数や他の共変数を調整しても，EQ-5D のスコアと有意に関連していた．すなわち，身体化傾向の高いグループほど，EQ-5D のスコアが低かった．

②予防に有用な福祉機器等の開発

1. 体幹部と腰部との関係性に，体幹部と頭部との関係を付加考慮することで，頸部に起因するストレートネック等の関連する症状も把握できることがわかった．これらの機能を組み込んだ第 2 次「治療モデル不良姿勢チェッカー」を試作評価した結果，不良姿勢改善の再現性において良好な結果を得ることができた．第 2 次「治療モデル不良姿勢チェッカー」を介護現場での腰痛の前兆となる腰痛リスクの可視化を検討したが，介護現場においては重量物の運搬等，姿勢のみでは判断できない介護者への負担という新しいリスクを考慮する必要があることがわかった． また運搬等の動作分析から負担部位を特定し，それらの部位を主動している脊柱起立筋の筋活動を介護業務中に監視する機能を有する，「予防モデル不良姿勢チェッカー」を作製した．「予防モデル不良姿勢チェッカー」では脊柱起立筋を指標として作業現場で姿勢のみならず腰部負担を計測し，かつ負担量が大きい作業員の位置を特定する仕組みまで構築した．

2. 腰椎MRI所見と過去の高度な腰痛の既往との関連を年齢・性を調整して解析した結果、Pfirrmann分類≧3、椎間板膨隆あり、High intensity zone(HIZ)あり、が過去の高度な腰痛の既往と関連していた。 これらの知見は、腰痛スクリーニングに活用可能であり、予防アルゴリズムの一角を担うものと考えている。
3. 開発した福祉機器（新たなコンセプトの体幹装具）の着用で、補足運動野は歩行安定期により早期に有意に低下した。また左右の運動前野は、歩行安定期により晩期に低下した。以上により装具の着用で垂直姿勢の維持や運動制御に関わる高次運動野の活動が修飾されることが明らかになった。

③介護看護従事者への予防介入とマネジメントシステムの構築

6か月後の追跡調査時の、各群の回収数はA群949名、B群706名、C群751名、計2,406名であり、追跡率はそれぞれ 71.9%、70.6%、67.0%で、全体では 70.0%あった。腰痛と関連情報を把握するためのアンケート調査を行った結果、腰痛の自覚症状改善の割合は,A群で13.3%、B群で23.5%、C群で22.6%と介入群で上昇していた。また腰痛予防対策の実行度はコントロール群で低くなっていた。腰痛の改善を目的変数として、背景を調整しても介入治療効果が認められるかに関して多変量解析（Logistic 回帰分析）を用いて検討した。雇用の安定等に関する法律（高年齢者雇用安定法）をもとに、45歳以上を「中高年齢者」と、またBMI 25以上を肥満と定義した。この結果、Bの介入（腰椎伸展体操の普及・実践)、C の介入（Bの介入+産業理学療法士による腰痛教育・相談の実践）とも有意に腰痛を改善（コントロール群の約2倍）することが分かった。またFABQが15点未満であることは腰痛改善の因子であることが明らかになった。

④個人と職場の双方に有益な腰痛治療と職業生活との両立支援手法の開発

産業理学療法士によるメール指導は、相談者の腰痛予防のための行動変容を促すのに有用と思われているものの介入群および対照群において，全ての一般特性の項目に有意な差は認めなかった．各群において，介入/観察前後の全ての項目に有意差は認めなかった．また，2 群間の変化量についても全ての項目に有意な差を認めなかった．

腰痛予防を目的とした教育教材を開発し，これらをインターネットやSNSを利用して普及啓発した．今後は，これらの効果的な使い方（労働者への教育方法や労働環境への導入方法など）を検討し，人的手段あるいはインターネットによる教育教材を使用する側（指導者側）の教育も継続しなければならないと考えている.

⑤労働安全衛生マネジメントシステム構築を視野に入れた提言作成

作成した成果物を本稿章末に提示する。

D. 考察

介護の現場では、腰痛有訴者が多く、身体的負荷のみならず、ストレス反応としての活気、疲労感、抑うつ感、身体愁訴が関連することが浮き彫りになった。

作業に支障をきたす腰痛が遷延化することに影響する要因は、仕事や生活での満足度が低い、働きがいが乏しい、不安感が強いといった、職場を主とする心理社会的要因であることが明らかになったが、本知見は、欧米のエビデンスと矛盾しない。メカニズムとしては、心理社会的要因がストレッサーとなり，中脳辺縁系ドパミン・オピオイドシステムの機能異常に続発する下行性疼痛調節系や自律神経系のアンバランスに伴う痛覚過敏や局所の血流低下・筋攣縮などが考えられる。その結果として、複数の身体愁訴（いわゆる身体化、腰痛はその一症状）が出現したり遷延化

する場合があるのだろう。

我が国の産業衛生分野において、人間工学的なアプローチによる腰痛の予防や対策が主流であり、重要なアプローチであることは疑いない。しかしながら、厚生労働省業務上疾病発生状況等調査にて、腰痛における休業4日以上の業務上疾病の発生件数をはじめとする統計データが長年にわたり好転していない現状を踏まえると、作業支障腰痛の遷延化による職場における労働力の損失を予防・緩和するための今後の対策として、心理社会的要因へのアプローチも人間工学的アプローチと並行して考慮する必要がある。本研究では疫学的な分析を積み重ね、リスク要因に関するエビデンスを構築し提言を作成するまでにいたった。この成果物は今後の腰痛予防のマイルストーンになるものと自負している。

予防に有効な福祉機器の開発に関してであるが、新たなコンセプトで開発した体幹装具（TS）着用で、補足運動野は歩行安定期により早期に有意に低下し、左右の運動前野は、歩行安定期により晩期に低下したことから装具の着用で垂直姿勢の維持や運動制御に関わる高次運動野の活動が修飾されることが明らかになった。

本研究ではさらに今適度な骨盤前傾と体幹伸展の姿勢では腰部負担が小さくなることがわかったため，この姿勢をとることをフィードバックする「不良姿勢チェッカー」を作製した。当初目的としていたエビデンスに基づく体幹装具に代わる新たな姿勢を修正する機器の開発だけでなく，これを発展させた機器の開発まで3か年内に達成することができ，本プロジェクトは順調に推移したものと考えている。

また本研究では、国内外に類を見ない腰痛予防運動の大規模な介入研究を施行した。これは12労災病院の協力なくしては得られなかった成果であり、研究代表者が提唱する腰痛予防法のエビデンスを確立するための代表的な研究となることが予想される。

さらには、腰痛に関わる両立支援を推進するうえで、運動器およびリハビリテーション医学の領域に加え、産業保険分野に精通している産業理学療法士が実施するメール指導は、腰痛予防のための行動変容を促すことから、その質の高いシステムを構築された。

以上の成果物をもとに、これらが普及することによって腰痛対策を新たなステージに進めることができるのではないかと考えている。今後、広報も含め積極的な展開を予定している。

E. 結論

最終的な本研究グループの活動成果として効率的かつ包括的な作業関連性腰痛の予防対策の提言を作成した。同提言は、社会・医療経済面、更には労災補償面にも大きく貢献するものと考えている。

F. 健康危険情報

該当なし

G. 研究発表

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Harris EC, Serra C, Martinez JM, Delclos G, Benavides FG, Carugno M, Ferrario MM, Pesatori AC, Chatzi L, Bitsios P, Kogevinas M, Oha K, Freimann T, Sadeghian A, Peiris-John RJ, Sathiakumar N, Wickremasinghe AR, Yoshimura N, Kelsall HL, Hoe VC, Urquhart DM, Derrett S, McBride D, Herbison P, Gray A, Salazar Vega EJ.: Classification of neck/shoulder pain in epidemiological research a comparison of personal and occupational characteristics, disability and prognosis among 12,195 workers from 18 countries. Pain 157: 1028-36, 2016

2. 学会発表
なし

H. 知的財産権の出願・登録状況（予定を含む）
１．特許取得
なし
２．実用新案登録
なし
３．その他

Ⅱ.分担研究報告

労災疾病臨床研究事業費補助金

分担研究報告書

医療介護職場における腰痛の現状と心理社会的要因の関連性の検討

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研究要旨

勤労者における腰痛は、個人の健康問題だけでなく労働生産性の低下による社会経済的にも大きな問題である。厚生労働省の調査によると、腰痛により休業を余儀なくされる件数は保健衛生業領域においてこの 10 年で約 2.7 倍と顕著な増加を辿っており、介護・看護従事者への腰痛対策は、産業衛生領域の喫緊の課題といえる。勤労者の腰痛の要因には、腰自体への負担に関わる問題に加え，様々な心理・社会的要因が重要なことが明らかになってきている。

本研究では、単一医療介護施設の職員を対象に、自記式調査票を用いた横断研究において、腰痛の現状およびその関連因子について心理社会的要因を中心に探索することとした。対象者 203 名のうち、仕事に支障をきたした腰痛経験者は 36 名（17.7%）であった。腰痛の有無別に各評価項目の群間比較を行った結果、FABQ（恐怖回避思考が強い）、SSS-8（身体症状が強い）、職場での対人関係でのストレスに有意差を認めた。多要因を調整したロジスティック解析においても、上記 3 要因が有意な因子として抽出された。職場での腰痛対策には、上記の心理社会面に配慮した介入が必要であることが示唆された。

A. 研究目的

腰痛は世界共通の健康問題であり、特に勤労者においては腰痛が労働生産性の低下の主要因とされている。また、世界疾病負担研究において、腰痛は、障害生存年数（Years Lived with Disability)、つまり健康でない状態で生活する年数を指標とする統計で、289 の疾患や傷病の中でトップに位置しており、社会的損失や健康面への影響が大きい腰痛への対策は世界的に重要な課題といえる。

厚生労働省の発表した業務上疾病発生状況等調査によると、腰痛により 4 日以上を休職した業務上疾病の発生件数は、全職業性疾病の約 6 割を占め第 1 位となっている。業種別にみると、運輸交通業、保健衛生業、製造業、商業・金融・広告業、貨物取扱業などが、業務上疾病による腰痛発生が多く、特に近年では、保健衛生業の腰痛が 10 年で 2.7 倍という最も顕著な増加となっており、医療介護現場での腰痛対策は喫緊の課題といえる。

上記を踏まえ、平成 6 年に厚生労働省から発表されていた「腰痛予防対策指針」（2013 年）が 19 年ぶりに改訂され、新指針では適用対象を拡大し、福祉・医療分野における介護・看護作業も対象となった。また、新指針での変更点で注目すべきは、腰痛の新規発症要因として「動作要因」「環境要因」「個人的要因」に加えて、「心理・社会的要因」が追加されたことである。これまでの腰痛発症に関する研究は、身体的負荷など人間工学的側面に重点を置いて検討されていたが、近年では精神的

ストレスや職場での対人関係など心理社会的要因も腰痛の発症に影響することが明らかとなってきている。

本研究では、保健衛生業領域における適切な腰痛対策を検討する基礎資料として、医療介護現場における腰痛の実態調査および腰痛に関連する心理社会的要因を網羅的に探索することとした。

B. 研究方法

研究デザインは横断研究とした。対象は、某医療法人社団の職員 280 名とし、無記名の自記式質問票を郵送にて回収した。

調査項目は、基本情報（年齢・性別・BMI・職種）、腰痛の有無、仕事のストレス要因（職業性ストレス簡易調査票より抜粋）、心の健康状態（K6）、恐怖回避思考（Fear-Avoidance Beliefs Questionnaire:FABQ)、身体症状(Somatic Symptom Scale-8：SSS-8)、仕事依存度である。腰痛における disability の程度は 4 段階とした(Grade 1、腰痛はなかった；Grade 2、腰痛はあったが仕事に支障はなかった；Grade 3、腰痛のため仕事に支障をきたしたこともあったが休職はしなかった；Grade 4、腰痛のため休職したことがある)。本研究では、disability の強い（仕事への支障度が高い）腰痛に注目するため、仕事に支障をきたす群（Grade 3、4）とそうでない群（Grade 1、2）の 2 群に分けて解析を行った。仕事に支障をきたす腰痛の有無により、各評価項目を群間比較（t 検定、Fisher 正確検定）し、その後、腰痛の有無を目的変数、各評価項目を説明変数として、傾向スコアで調整するロジスティック回帰モデルで解析を行った。

C. 研究結果

アンケートの有効回答者数 203 名（72.5%）であった。平均年齢は 39.8 歳（SD 12.2)、性別は 70%が女性であった。63.1%が看護および介護業務職であった（表 1)。

表 1　対象者の属性（n = 203）

		n (%)
年齢(歳), 平均(SD)		39.8 (12.2)
性別	男性	61 (30.0)
	女性	142 (70.0)
BMI, 平均(SD)		22.6 (4.1)
職業	看護･介護関係	128 (63.1)
	それ以外	75 (36.9)
恐怖回避思考(FABQ)	Low	172 (85.6)
	High	29 (14.4)
仕事満足度	Not satisfied	51 (26.2)
	Satisfied	144 (73.8)
仕事負担量	Not stressed	126 (62.7)
	Stressed	75 (37.3)
職場での対人関係ストレス	Not stressed	163 (81.5)
	Stressed	37 (18.5)
仕事のコントロール度	Cotrolled	147 (72.8)
	Not controlled	55 (27.2)
上司からのサポート	Supported	114 (57.6)
	Not supported	84 (42.4)
同僚からのサポート	Supported	151 (75.9)
	Not supported	48 (24.1)
家族、友人からのサポート	Supported	58 (29.1)
	Not supported	141 (70.9)
心の健康状態(K6)	Low	103 (50.7)
	Middle	54 (26.6)
	High	46 (22.7)
身体症状(SSS-8)	other	128 (64.0)
	Very high	72 (36.0)
仕事依存度	Low	63 (31.2)
	Middle	73 (36.1)
	High	66 (32.7)

対象者のうち、仕事に支障をきたした腰痛経験者は 36 名（17.7%）であった。上記腰痛経験者の群とそれ以外の群で、各調査項目について群間比較を行ったところ、FABQ（恐怖回避思考、p = 0.037)、SSS-8（身体症状、p = 0.0003)、職場での対人関係ストレス（p = 0.022）が統計学的な有意差を認めた。年齢、性別、BMI、職業を調整したロジスティック解析においても、上記 3 要因が有意な因子として抽出された（表 2)。

表 2　多重ロジスティック解析により抽出された要因

要因	Adjusted OR	95% CI	*p*-value
恐怖回避思考	2.619	1.003-6.538	0.049
対人関係ストレス	2.619	1.067-6.224	0.036
身体症状	4.034	1.819-9.337	< 0.001

D. 考察

産業衛生領域の腰痛対策を効率的に行うための基礎資料として、単一医療介護施設職員に対して、腰痛の実態およびその関連要因について心理社会的要因を中心にアンケート調査を行った。対象者の17.7%が仕事に支障をきたす腰痛を経験していた。腰痛の関連要因として、恐怖回避思考、身体症状、職場での対人関係ストレスが抽出された。

恐怖回避思考とは、痛みに対する強い不安感や恐怖感から活動を過剰に制限（回避）してしまう思考のことをいう。腰痛の慢性化の予後規定因子である心理社会的要因（yellow flag sign）の中でも、この恐怖回避思考は機能障害や就業状況の予後に強く影響し、最も重要視すべきものとされている。勤労者の腰痛を慢性化させないために、上記概念を考慮した早期のスクリーニングが必要と考えられる。

今回の研究では、身体症状が高いオッズ比を示した。身体症状は、一般に精神の症状が身体の不調・不具合として身体化したものであり、頭痛、眩暈、胃腸の不調、疲労・活力低下といった愁訴として報告されている。これらは心理的ストレスが脳機能に影響を与えることにより生じる症状であり、腰痛にも心理的ストレスによる脳機能の不具合（dysfunction）を介し、筋緊張などの局所症状が強まる可能性があると思われる。身体症状は筋骨格系疼痛などの健康状態と関連があるとされており、また腰痛慢性化の一因であるとの報告が増えてきている。心理・社会的要因の強い腰痛では、さまざまな身体症状をあわせもつ場合が想定されるため、診療では注意深く問診することが必要であると考えている。

本結果では、職場での対人関係ストレスも仕事に支障をきたす腰痛との関連が示唆された。我が国の5310名の勤労者を対象としたコホート研究において、仕事関連ストレスが腰痛の発症および慢性化に影響することが示されており、職場での腰痛対策にはストレス要因を包含する必要がある。厚生労働省が発表している「腰痛予防対策指針（2013)」の中にも、「職場の対人ストレスに代表される心理社会的要因」との記載があり、対人関係ストレスが腰痛における重要な因子であることがわかる。

E. 結論

本研究では、医療介護職場における腰痛の関連因子は、恐怖回避思考・身体症状・対人関係でのストレスであった。職場での腰痛対策には、上記の心理社会面に配慮した介入が必要であることが示唆された。

F. 健康危険情報

該当なし

G. 研究発表

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H. 知的財産権の出願・登録状況（予定を含む）

該当なし

1. 特許取得

該当なし

2. 実用新案登録

該当なし

3. その他

該当なし

労災疾病臨床研究事業費補助金

分担研究報告書

介護看護従事者の腰痛に関わる実態およびリスクの同定

-慢性腰痛患者のQOLと、身体化症状およびうつとの関連-

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研究要旨

抑うつは腰痛の重要な危険因子であり，腰痛のアウトカムとも関連している．身体化（somatization）はしばしば抑うつに合併する心理的因子である．過去の研究で，身体化も腰痛に影響していることが示唆されている．この研究の目的は，慢性腰痛のある人において，身体化が，抑うつと独立して，健康関連QOLと関係があるかを検討することである．

心身の健康に関するインターネット調査に参加し，慢性腰痛のあった20-64歳の日本人（n=3,100）が対象である．健康関連QOLはEuroQol 5 Dimension (EQ-5D)で，身体化は日本語版Somatic Symptom Scale-8 (SSS-8)で，抑うつ症状はPatient Health Questionnaire-2 (PHQ-2)で評価した．身体化と健康関連QOLの関係を，線形回帰モデルで検討した．解析は抑うつ，年齢，性別，BMI，喫煙，婚姻，学歴，定期的な運動，雇用状況，通院していた疾患の個数（0－25）を調整した．

身体化は抑うつを調整しても健康関連QOLと有意に関係していた．すなわち，慢性腰痛のある日本人で，身体化傾向の強い人ほど，EQ-5Dのスコアが低かった（pトレンド<0.001）．

A.研究目的

腰痛は有訴率が高く，生涯有病率は約 80%だったという報告がある (1).　世界的に見ても，腰痛は障害生存年数（years lived with disability YLDs）の原因の第 1 位である (2). 腰痛には身体的，心理社会的要因など複数の要因が関与している (3-5). その中でも抑うつは腰痛発症の危険因子であるとともに，腰痛の慢性化の予測因子でもある (4, 6). 慢性腰痛の患者の中でも，抑うつのある患者ではない患者よりも生活の質が低いという報告がある (7). また直接的な医療費も，抑うつのある腰痛患者の方が無い患者よりも高い (8). そのため，医療現場で腰痛患者の抑うつ症状を評価することは，予後の判定や治療の選択に重要であると考えられる．

身体化（somatization）とは，心理的ストレスに反応して，身体症状の不安を訴え，治療を求める傾向であるとされ (9)，しばしば抑うつに合併する (10). 過去の我々の研究で，身体化傾向は軽度の腰痛のあった人達の中で，持続する腰痛を発症することの予測因子であった (11). 他の研究では，身体化傾向が腰痛患者の治療アウトカムと関連していた (12). 腰痛と抑うつについての過去の研究は散見されるものの，慢性腰痛における身体化の役割についてはあまりよく分かっていない．

頻度の高い身体症状を評価するための，自己申告式質問票は複数存在するが，最近のシステマティックレビューは Patient Health Questionnaire-15 (PHQ-15) と 12 項目の Symptom Checklist-90 somatization scale が大規模研究では最も適切であ

ると報告している (13). この 2 つの質問票は，重要な身体症状を含んでいながら比較的短く，かつ心理学的特性が確立されている. Somatic Symptom Scale-8 (SSS-8) は PHQ-15 の 8 項目から作成された. この研究の目的は，慢性腰痛のある日本人において, SSS-8 をもちいて評価した身体化傾向が，抑うつを考慮しても，健康関連 QOL と関連しているかを検討することである.

B. 研究方法

この研究の対象は慢性腰痛のある 20-64 歳の日本人 3100 人である. 2015 年にインターネットにて実施された「心身の健康に関する調査」のデータを用いた. 参加者はインターネット調査会社（United Inc.）により募集された. 年齢が 20-64 歳である約 125 万人の中から, 27 万人を無作為に抽出し，e-mail でオンライン調査への協力を求めた.

調査では，過去 4 週間に生理，妊娠，または風邪に関係しない腰痛があったかをたずねた. そのために日常生活や社会活動に支障を来した腰痛が 3 か月以上続いたものを，慢性腰痛ありと定義した.

身体化は日本語版 SSS-8 を用いて評価した. SSS-8 は自己記入式の質問票で，身体症状の有無と重症度を評価するものである (14). SSS-8 は DSM-5 のフィールドトライアルで, 身体表現性障害（somatic symptom disorder） の診断を容易にするために用いられ (15), その後 SSS-8 は世界各地で使用されている (16-21). ドイツ語版の SSS-8 はドイツの一般国民において，信頼性と妥当性が良好であったと報告されている (22). 我々は英語版の SSS-8 を日本語に訳し (23)，言語的，心理測定的妥当性を確認した (24). SSS-8 の合計点は, Gierk らの文献と同様に, 無 - 僅か (0-3), 低 (4-7), 中 (8-11)，高 (12-15) ，非常に高 (16-32)に分けた (22).

抑うつ症状は Patient Health Questionnaire-9（PHQ-9）から抽出した 2 問からなる PHQ-2 を用いて評価した (25). これは，過去 2 週間に抑うつや失感情症を体験したかを問うものである. PHQ-2 の原著では各質問は 0－3 のスケールで評価されるが，我々は各質問を有り／無しの 2 段階で評価する，国立精神・神経医療研究センターによるものを用いた (26). よって PHQ-2 の合計点は 0，1，または 2 である.

健康関連 QOL は，全般的な健康状態を測定する，EuroQol 5 Dimension (EQ-5D) を用いて評価した (27). これは移動，セルフケア，日常活動，痛み／不快，不安／抑うつを問う，5 つの質問からなる (27). 回答は全般的な健康状態を表す，-0.11 から 1.00 までの 1 つのスコアに変換される. 1 は完全に健康な状態で，0 は死である. 日本語版 EQ-5D は EuroQol グループに承認されており，広く研究に用いられている (28).

調査では，年齢，性別，身長，体重，婚姻，学歴，雇用状況，喫煙の有無についてたずねた. 身長, 体重より BMI を計算した. また過去 1 年間に, 30 分以上の運動をした頻度（週 2 回以上，週 1 回程度，月 1-2 回程度，していなかった）をたずねた. 週 2 回以上と答えたものを，定期的な運動ありと定義した. また，27 の疾患について，通院しているかをたずねた（心臓の病気，高血圧，高脂血症，肺の病気，糖尿病，胃腸の病気，腎臓の病気，肝臓の病気，貧血などの血液の病気，甲状腺の病気，ガン，うつなどのメンタルの病気，婦人

科系の病気，泌尿器科系の病気，皮膚の病気，睡眠時無呼吸症候群，耳鼻科の病気，眼科の病気，虫歯や口腔内の病気，変形性関節症，腰痛，頭痛，関節リウマチ，線維筋痛症，骨粗しょう症，肥満症，その他）．腰痛とうつなどのメンタルヘルスの病気以外の 25 の疾患のうちで，通院ありと答えた疾患の個数を求めた．

SSS-8（5 カテゴリ）と EQ-5D スコアの関係は，線形回帰モデルで検討した．抑うつ（PHQ-2）も同じモデルに入れて解析した．SSS-8 と PHQ-2 の交互作用は統計的に優位でなかったので，最終モデルには含めなかった．最終的な多変量モデルでは，年齢，性別，BMI，喫煙，婚姻，学歴（短大以上か），定期的な運動の有無，雇用状況（正規雇用かそれ以外か），通院していた疾患の個数（0－25）を調整した．これらの変数は，この研究のデータで統計学的に有意であるかではなく，過去の文献をもとにあらかじめ決定した．これらの変数の VIF から，あきらかな多重共線性の問題はみとめられなかった．解析はすべて SAS9.4 を用いて行い，両側検定で $p<0.05$ を統計学的に有意とみなした．

C. 研究結果

参加者の特徴を表 1 に示す．参加者は平均 44.5±11.2 歳で，48%が女性であった．PHQ-2 は 1576 人(51%) が 0, 632 人(20%)が 1, 892 人 (29%)が 2 であった．EQ-5D は平均 0.78±0.18 であり，PHQ-2 の点数が高くなるほど低かった． SSS-8 の平均スコアは 9.67±6.68 で，PHQ-2 の点数が高くなるほど，SSS-8 が非常に高い（≥16）の割合が高かった．

多変量解析の結果を表 2 に示す．PHQ-2 の点数は EQ-5D のスコアと有意に関連していた．SSS-8 のどのカテゴリに属するかは，PHQ-2 の点数や他の共変数を調整しても，EQ-5D のスコアと有意に関連していた．すなわち，身体化傾向の高いグループほど，EQ-5D のスコアが低かった．

D. 考察

この研究により，慢性腰痛のある日本人の成人において，身体化傾向が高いほど，健康関連 QOL の指標である EQ-5D のスコアが低く，この関係は抑うつ症状や他の通院中の疾患を調整しても有意であることが明らかになった．

身体化，抑うつ，不安症はプライマリケアの現場でよく見られる精神疾患であり，これらはしばしば合併する (10)．しかし，それぞれが独自に，健康関連 QOL と関連している可能性が示唆されている． Lowe らは，プライマリケアクリニックの患者で，抑うつ，不安症，身体化のそれぞれが独立して，Short-Form General Health Survey（SF-20）のスコアと関連があったと報告しているが，それぞれの効果量（effect size）は少～中等量であった (10)．9 のポピュレーション研究のレビューは，身体症状の総合スコアは，抑うつ，不安症，一般的な疾病を調整しても，医療機関の利用と関連しており，健康状態の予測因子であったと報告している (29)．我々の研究では，日本人の慢性腰痛のある人に限っても，身体化傾向が，抑うつや並存疾患を考慮したうえで，健康関連 QOL と有意に関係していることが示された．

先行研究から，身体化が腰痛のアウトカムに影響している可能性が示唆されている (6)．松平らは，軽度の腰痛をもつ日本の都市部の勤労者において，職業性ストレス簡易調査表により評価し

た身体化傾向が，持続性腰痛の発症を予測したことを報告した (11)．また，海外の研究では，カイロプラクティックで治療された腰痛患者で，身体化が痛みの強さ，身体機能，自覚的回復と関連していた (30)．病院で治療された腰痛患者でも，手術あるいは保存的治療を受けたかによらず，ベースラインの身体化は，1 年後の SF-36 と相関し，痛みが 50%以上軽減したかどうかと関連していた (12)．しかしこれらの先行研究では，抑うつは必ずしも調整されていない． 抑うつは腰痛の発症と慢性化の危険因子であり(4, 6), 身体化はしばしば抑うつに合併するので，身体化が抑うつと独立して，腰痛のアウトカムと関連しているかを明らかにすることは容易ではないかもしれない．

この研究では，標本数が多く，重要な共変数も調整している．参加者は医療機関の患者ではないため，治療を求めたという特異性によるバイアスの可能性も低い．しかし，抑うつの評価は 2 つの質問によるもので，誤分類があり得る．また本研究では不安症は評価していない．そのため，抑うつや不安症による交絡が残存している可能性はある．また，この研究の参加者はインターネットで募集されたため，結果は日本人全体に一般化することは出来ないかもしれない．

E. 結論

慢性腰痛のある人で，抑うつ症状を調整しても，身体化傾向の強い人ほど，健康関連 QOL が低かった．

Ｆ．健康危険情報

特記すべき事項なし。

Ｇ．研究発表

現時点ではなし。

Ｈ．知的財産権の出願・登録状況

現時点ではなし。

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表 1 慢性腰痛のある参加者の特徴

	全員 (n=3100)	**PHQ-2=0 (n=1576)**	**PHQ-2=1 (n=632)**	**PHQ-2=2 (n=892)**	***p 値**
平均年齢(SD)	44.5 (11.2)	45.8 (11.0)	44.5 (11.5)	42.1 (11.1)	<0.001
女性 (%)	1483 (47.8)	743 (47.1)	311 (49.2)	429 (48.1)	0.669
BMI (%)					0.018
<25	2333 (75.3)	1184 (75.1)	484 (76.6)	665 (74.6)	
25 - 29	589 (19.0)	320 (20.3)	103 (16.3)	166 (18.6)	
≥30	178 (5.7)	72 (4.6)	45 (7.1)	61 (6.8)	
現在の喫煙 (%)					<0.001
あり	1064 (34.3)	489 (31.0)	233 (36.9)	342 (38.3)	
なし	2036 (65.7)	1087 (69.0)	399 (63.1)	550 (61.7)	
現在の婚姻 (%)					<0.001

なし	1327 (42.8)	544 (34.5)	299 (47.3)	484 (54.3)	
あし	1773 (57.2)	1032 (65.5)	333 (52.7)	408 (45.7)	
学歴 (%)					0.043
短大未満	1650 (53.2)	804 (51.0)	350 (55.4)	496 (55.6)	
短大以上	1450 (46.8)	772 (49.0)	282 (44.6)	396 (44.4)	
定期的な運動 (%)					0.001
なし	2487 (80.2)	1222 (77.5)	524 (82.9)	741 (83.1)	
あり	613 (19.8)	354 (22.5)	108 (17.1)	151 (16.9)	
雇用形態 (%)					<0.001
正規職員	1271 (41.0)	700 (44.4)	221 (35)	350 (39.2)	
それ以外	1829 (59.0)	876 (55.6)	411 (65)	542 (60.8)	
通院疾患の平均個数 (SD)	1.2 (2.0)	1.0 (1.8)	1.3 (2.0)	1.4 (2.3)	<0.001
EQ-5D 平均 (SD)	0.78 (0.18)	0.84 (0.16)	0.75 (0.17)	0.70 (0.17)	<0.001
SSS-8 (%)					<0.001
無 - 僅か	590 (19.0)	445 (28.2)	77 (12.2)	68 (7.6)	
低	785 (25.3)	488 (31.0)	152 (24.1)	145 (16.3)	
中	616 (19.9)	297 (18.9)	156 (24.7)	163 (18.3)	
高	505 (16.3)	186 (11.8)	122 (19.3)	197 (22.1)	
非常に高	604 (19.5)	160 (10.2)	125 (19.8)	319 (35.8)	

表 2. EQ-5D と SSS-8 の関係（多変量解析）

	回帰係数	標準誤差	p 値	トレンド p
切片	0.815	0.014	<0.001	
SSS-8				<0.001
無 - 僅か	0.218	0.009	<0.001	
低	0.142	0.008	<0.001	
中	0.098	0.009	<0.001	
高	0.040	0.009	<0.001	
非常に高	レファレンス			
PHQ-2				
0	レファレンス			
1	-0.042	0.007	<0.001	
2	-0.066	0.007	<0.001	

労災疾病臨床研究事業費補助金

分担研究報告書

腰部負担を軽減する「不良姿勢チェッカー」の開発

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研究要旨

産業衛生分野においても腰痛の予防や軽減を目的として腰ベルトやコルセットに代表される体幹装具が使用されている．コルセットや他の現存の体幹装具は腹部を圧迫する装具や３点で固定する装具に大別される．我が国でも産業衛生分野だけでなく，臨床場面でも体幹装具は腰痛の予防や治療を目的として，数多く使用されているが，装着による効果のエビデンスは十分でない．従来，腰部に何らかの痛みや違和感を訴える症状には，腰部を固定し安静にすることが主とした対応であったが，固定と安静はむしろ対象者に備わっている体幹機能を弱化させる恐れがある．

本研究では，腰部負担を軽減する方法として「良姿勢」に着目し，本助成を受けて初年度と２年目に実施した３次元動作解析，筋電計，超音波画像診断装置を用いて明らかにした腰部負担因子を腰痛リスクとして可視化し，フィードバックに用いることに成功した．腰痛リスクの可視化は，治療および予防の場面において重要な要素であり，労災の予防と治療の効果を高めると考えられる．

A．研究目的

腰ベルトやコルセットに代表される体幹装具使用による腰痛の治療と予防は産業衛生分野においても行われている．しかしながら，体幹装具使用による腰痛予防や治療のエビデンスは乏しく，最近では長期間装着すると姿勢安定に寄与する体幹深部筋の弱化を招いてしまうという報告もある．また，従来は腰部に何らの痛みや，違和感を訴える症状に対して腰部を固定し安静にすることが主とした対応であったが，固定と安静は本来腰部が持つ活動を阻害する可能性が高い．

本研究では，腰部の負担を軽減する方法として「良姿勢」に着目し，初年度と 2 年目に実施した 3 次元動作解析，筋電計，超音波画像診断装置を用いた計測によって得られたエビデンスを基に，腰部への負担を増加させる負担因子を同定した．本研究ではこの負担負担因子を可視化することで，作業場面や臨床現場で使用でき，尚且つそれらの状況をフィードバックできる機器を開発することを目的とする．

B．研究方法

本研究においては大掛かりな実験機器が無い作業場面や介護現場で不良姿勢を判断する手法を開発する必要があるが，臨床現場には大きく，病院などで医師が患者に対して行う治療現場と，介護施設等で管理者が施設職員に対して腰痛を予防する為の介護予防現場の 2 つが想定されることから，上記 2 つの現場に対する不良姿勢を判断する手法を開発する．

①　治療モデル

治療においては，患者が自身の腰痛に関わる姿勢の状態を把握し，問題のある姿勢の除去及び，それらを日常生活場面において，継続することが求められる．

従来のリハビリの現場で行われている鏡などを用いた簡便な姿勢理解では前額面や矢状面と

いった一義的な姿勢の理解のみに留まり多面的に発生している姿勢の問題を理解することは難しい．そこで腰痛に関連する姿勢情報の特定とそれらの姿勢情報のみを取得することが可能な「不良姿勢チェッカー」を開発する．

② 介護予防モデル

治療モデルは治療現場での使用を想定し姿勢が悪化している状況を修正することを目的としているが，労働の現場においては悪化する前兆をとらえることが重要となる．

そこで前兆として現れる要素の特定と，要素を簡便に抽出する為の手法，さらにはそれらをフィードバックする技術に関する機器の開発を行う．

C．研究結果

①治療モデル

初年度と２年目の研究結果から，腰痛に関わる姿勢因子の中で特に，体幹部と腰部の位置関係が腰痛に関連することがわかった．そこでこれらのパラメータをフィードバックに用いる為に，体幹上部の肩部と腰部に電気的に角度を計測する姿勢計測用具を試作した．

治療モデルに用いる「治療モデル不良姿勢チェッカー」は，スマートフォンと連動しており電子的に送信される角度情報からスマートフォン内の疑似モデルが対象者と同様の姿勢を表現することで，自身の姿勢の状況の理解が可能となる仕組みである．これらを実際の臨床現場で評価した結果，体幹部と腰部との関係性に，体幹部と頭部との関係を付加考慮することで，頸部に起因するストレートネック等の関連する症状も把握できることがわかった．これらの機能を組み込んだ第2次「治療モデル不良姿勢チェッカー」を試作評価した結果，不良姿勢改善の再現性において良好な結果を得ることができた．

②介護予防モデル

治療モデルにて試作した姿勢計測用具を用い介護現場での腰痛の前兆となる腰痛リスクの可視化を検討したが，介護現場においては重量物の運搬等，姿勢のみでは判断できない介護者への負担という新しいリスクを考慮する必要があることがわかった．そこで，運搬等の動作分析から負担部位を特定し，それらの部位を主動している脊柱起立筋の筋活動を介護業務中に監視する機能を有する，「予防モデル不良姿勢チェッカー」を作製した．「予防モデル不良姿勢チェッカー」では脊柱起立筋を指標として作業現場で姿勢のみならず腰部負担を計測し，かつ負担量が大きい作業員の位置を特定する仕組みまで構築した．

生体信号計測ユニットは，左右の脊柱起立筋の活動を 1000Hz でモニタリングし，筋活動データに対して RMS(二乗平均平方根)処理を行い定量化する．１sec 当たりの定量化された筋活動をリスク指標として用い，位置情報と同時に記録，表示することで位置と腰痛リスクを時系列で把握するシステムを開発した．

D．考察

「治療モデル不良姿勢チェッカー」開発においては従来鏡等を用いない限りは難しかった歩行や日常生活時の自身の姿勢を IOT の技術を用いることで簡便に理解し管理できるようになった．このことは，今後 IOT 技術の医療分野へ利活用を促す要因ともなり，労働安全衛生を含む臨床現場での腰痛治療効果と合わせて良い効果が期待できる．

「予防モデル姿勢チェッカー」においては，位置情報と脊柱起立筋の活動状況から，介護者を含む作業者の腰痛訴えが起こる前に，管理者が事前に危険因子を把握し対応することが可能となることから，労働者保護の観点からも普及を後押しする必要があると考えられる．

E．結論

腰部負担を軽減する手法として新しく姿勢をチェックすることが可能な姿勢計測用具と，介護

予防モデルとしては介護等職場内環境における腰痛リスクを可視化できるシステムを開発することができた.

F．健康危険情報

該当なし.

G．研究発表

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労災疾病臨床研究事業費補助金
分担研究報告書

腰椎 MRI 所見と過去の腰痛の既往との関連についての探索

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研究要旨

腰椎 MRI における椎間板変性所見と腰痛との関連についてはまだ議論がある。慢性腰痛の中には寛解と再発を繰り返すタイプの腰痛があることが知られている。本研究では、撮影時に腰痛のない参加者を対象として、腰椎 MRI 所見と過去の高度な腰痛の既往との関連を分析した。年齢・性を調整して解析した結果、Pfirrmann 分類≧3、椎間板膨隆あり、High intensity zone(HIZ)あり、が過去の高度な腰痛の既往と関連していた。

A.　研究目的

国民生活基礎調査では、腰痛は有訴率、通院率とも常に上位にある。我々が行った調査では、一生のうちに腰痛に罹患する割合は 83%、直近 4 週間での腰痛の罹患率は 36%である[1]。

腰椎の Magnetic Resonance Imaging(MRI)は腰痛の病態を評価するのに役立つが、椎間板の変性所見と撮影時に存在する腰痛との関連についてはまだ議論の一致がなく、椎間板変性所見が現在の腰痛と関連するという報告[2]と関連しないという報告[3]がある。

慢性腰痛はさまざまな経過をたどることが知られており、持続的な腰痛を呈する例の他に、寛解と再燃を繰り返す間欠的な腰痛を呈する例も存在する[4]。我々は、もし高度な腰痛が再燃することを推測させる MRI 所見を知ることができれば、そのような患者に選択的に腰痛予防の指導介入が可能になることを期待した。そこで、「MRI で椎間板変性所見があり、かつ撮影の時点で腰痛がないならば、椎間板変性の所見は過去の腰痛の既往を示し、高度な腰痛が再燃する可能性を示唆する」という仮説を立てた。本研究の目的は、撮影時に腰痛のない症例の腰椎 MRI 所見と過去の腰痛の既往との関連を調べることである。

B．研究方法

対象であるが、関東労災病院に勤務する職員で、MRI 撮影時に「腰痛がない」と申告された 91 例とした。「現在腰痛がない」ことは「１ヵ月以内に肋骨下縁から殿裂までの間の痛みがないもの」と定義した[5]。「過去に腰痛があった」ことは、ある程度高度な腰痛の既往があったことに限定するために、「医療機関へ通院するほどの腰痛があったもの」と定義した。自記式質問票を用いて年齢、性別、身長、体重を調査した。

MRI 所見の読影は、T12/L1 から L5/S1 の 6 椎間についてそれぞれ椎間板変性、椎間板膨隆、High intensity zone(HIZ)、すべりの有無を評価した。各所見について、少なくとも 1 椎間でみられるものを所見ありとした。

椎間板変性は Pfirrmann 分類（5 段階：1-5）[6]で 3、4、5 であるものとした。椎間板膨隆は 3mm 未満の椎間板腔の膨隆で矢状面像にて前後ともに同様に膨隆しているものとした[7]。HIZ は椎間板後方部分に、高信号を示す白い点状の所見があるものとした[8]。すべりは 5mm 以上すべっているものとした。

検者内信頼性を評価するために、無作為に選択された 20 例の MRI を 1 ヵ月以上の間隔を空けて 2 回読影した。検者間信頼性を評価するために、同様に無作為に選択された 20 例の MRI を 2 名の脊椎脊髄病指導医が読影した。検者内・検者間信頼性はκ値を用いて評価した。

MRI 撮影時に腰痛のない参加者 91 例を「過去に腰痛があった群」と「過去にも腰痛がなかった群」に分けて、MRI 所見との関連を評価した。さらに、単変量解析および年齢・性を調整した解析を行い、各 MRI 所見のオッズ比を算出した。

（倫理面への配慮）
関東労災病院医学研究倫理審査の承認を得て推進した。被験者に対してはデータを ID 化して管理するなど個人情報には十分配慮すること、同意後もいつでも同意撤回が可能であること等を説明後、書面での同意を取得した。

C．研究結果

91 名の参加者のうち 27 名には過去の腰痛の既往があり、64 名には過去の腰痛の既往がなかった。参加者全体の年齢は 34.9±10.6 才、女性 47 名・男性 44 名、BMI は 21.8±3.0 kg/m² であった。過去の腰痛がある群の平均年齢は 38.3 才、ない群は 33.5 才と有意差がみられた。性別、BMI は両群間で有意差がなかった(Table 1)。

Table 1 患者背景

Table 1. 患者背景

	全体 (n = 91)	過去の腰痛あり (n = 27)	過去の腰痛なし (n = 64)	*P*
年齢	34.9±10.6	38.3±10.7	33.5±10.4	0.0486*
女性 (%)	47 (51.6)	12 (44.4)	35 (54.7)	0.3718
BMI (kg/m²)	21.8±3.0	21.8±0.6	21.7±0.4	0.9639

検者内信頼性と検者間信頼性は、Pfirrmann 分類、椎間板膨隆はいずれも"moderate"、HIZ はいずれも"substantial"であり、一致度が高いことが示された[9]。すべりについては、2 名の読影者のうち 1 名の読影所見ですべりがあるとされた例がゼロであったため、κ 値の計算が不能だった(Table 2)。

Table 2　MRI 読影所見の検者内信頼性・検者間信頼性

Table 2.　MRI 読影の検者内信頼性・検者間信頼性

MRI 所見		読影数	Kappa 値	95%信頼区間
Pfirrmann 分類				
	検者内信頼性	20 vs 20	0.66	0.55-0.77
	検者間信頼性	20 vs 20	0.64	0.52-0.76
椎間板膨隆				
	検者内信頼性	20 vs 20	0.60	0.39-0.81
	検者間信頼性	20 vs 20	0.67	0.48-0.87
High intensity zone (HIZ)				
	検者内信頼性	20 vs 20	0.85	0.64-1.06
	検者間信頼性	20 vs 20	0.93	0.79-1.07
すべり				
	検者内信頼性	20 vs 20	NA	NA
	検者間信頼性	20 vs 20	NA	NA

Fisher 正確検定の結果、過去の腰痛がある群は、ない群と比べて、有意に Pfirrmann 分類≧3 (p=0.0026)、椎間板膨隆(p=0.0019)がみられた。HIZ とすべりには有意差がみられなかった(Table 3)。

Table 3 MRI 所見

Table 3. MRI 所見

	全体 (n = 91)	過去の腰痛あり (n = 27)	過去の腰痛なし (n = 64)	*P*
Pfirrmann 分類≧3	69 (75.8)	26 (96.3)	43 (67.2)	0.0026*
椎間板膨隆（＋）	48 (52.3)	21 (77.8)	27 (42.2)	0.0019*
High intensity zone (HIZ)（＋）	19 (20.9)	9 (33.3)	10 (15.6)	0.0883
すべり（＋）	4 (4.4)	3 (11.1)	1 (1.6)	0.0766

各椎間について着目すると、Pfirrmann 分類≧3 は T12/L1、L3/4、L4/5、L5/S1、椎間板膨隆は L2/3、L3/4、L4/5、L5/S1 で有意差がみられた（Table 4)。HIZ はほとんどすべて L4/5 または L5/S1 でみられた。すべりは L4/5 と L5/S1 のみでみられた。

Table 4 各椎間の Pfirrmann 分類と椎間板膨隆（MRI 所見）

Table 4. 各椎間の Pfirrmann 分類と椎間板膨隆（MRI 所見）

MRI 所見	高位	全体 (n = 91)	過去の腰痛あり (n = 27)	過去の腰痛なし (n = 64)	*P*
Pfirrmann 分類≧3	T12/L1	18 (19.8)	9 (33.3)	9 (14.1)	0.0350*
	L1/2	22 (24.2)	9 (33.3)	13 (20.3)	0.1851
	L2/3	30 (33.0)	10 (37.0)	20 (31.3)	0.5917
	L3/4	44 (48.4)	18 (66.7)	26 (40.6)	0.0232*
	L4/5	56 (61.5)	24 (88.9)	32 (50.0)	0.0005*
	L5/S1	56 (61.5)	23 (85.2)	33 (51.6)	0.0026*
椎間板膨隆（＋）	T12/L1	2 (2.2)	1 (3.7)	1 (1.6)	0.5245
	L1/2	1 (1.1)	1 (3.7)	0 (0.0)	0.1216
	L2/3	2 (2.2)	2 (7.4)	0 (0.0)	0.0277*
	L3/4	5 (5.5)	4 (14.8)	1 (1.6)	0.0113*
	L4/5	35 (38.5)	17 (63.0)	18 (28.1)	0.0018*
	L5/S1	35 (38.5)	16 (59.3)	19 (29.7)	0.0081*

単変量解析の結果、各オッズ比は Pfirrmann 分類≧3　12.7、椎間板膨隆 4.8、HIZ2.7、すべり 7.9 であり、Pfirrmann 分類≧3 (p=0.0009)と椎間板膨隆(p=0.0015)で有意差がみられた。年齢・性調整オッズ比を計算すると、各オッズ比は Pfirrmann 分類≧3　10.5、椎間板膨隆 4.2、HIZ3.1、すべり 6.6 であり、Pfirrmann 分類≧3 (p=0.0065)、椎間板膨隆(p=0.0047)、HIZ(p=0.0405)で有意差がみられた(Table 5)。

Table 5 単変量解析と年齢・性調節解析

Table 5. 単変量解析と年齢・性調節解析

	単変量解析			年齢・性調節解析		
	オッズ比	95%信頼区間	*P* 値	オッズ比	95%信頼区間	*P* 値
Pfirrmann 分類≧3	12.7	2.43-234.18	0.0009*	10.5	1.78-202.09	0.0065*
椎間板膨隆（＋）	4.8	1.79-14.55	0.0015*	4.2	1.54-13.15	0.0047*
High intensity zone (HIZ)（＋）	2.7	0.94-7.78	0.0652	3.1	1.05-9.42	0.0405*
すべり（＋）	7.9	0.96-163.50	0.0551	6.6	0.74-141.71	0.0923

D. 考察

両群間の背景には年齢以外に有意差がなかった。また、検者内信頼性と検者間信頼性は各所見について概ね良好とみなすことができた。

Pfirrmann 分類≧3 は特にオッズ比が 10 以上で

あり、過去の腰痛の既往と強く関連していた。椎間板変性はL5/S1とL4/5で生じやすいという過去の報告[10]と同様、本研究でも特に下位腰椎でPfirrmann分類≧3の所見がみられた。下位腰椎は上位腰椎と比較して可動域が小さいため[11]、椎間板に対する負荷が増大し変性を惹起するものと考えられた。椎間板膨隆も過去の腰痛の既往と関連していた。p 値は下位腰痛ほど低値になるものの、L2/3 以下のすべての椎間板レベルで椎間板膨隆は過去の腰痛の既往との関連がみられた。HIZ はFisher 正確検定と単変量解析では過去の腰痛の既往との関連はないという結果だったが、年齢・性を調整して解析すると有意に関連があるという結果になった。すべりは過去の腰痛の既往と関連がないという結果だったが、すべりのある例が少なかったことが結果に影響した可能性はある。

E．結論

腰椎MRIにおけるPfirrmann分類≧3、椎間板変性、HIZは過去の腰痛の既往と関連があった。すべりは関連がなかった。関連が示された所見は、高度な腰痛が再発する可能性を予測する所見の一部と考えられた。

F．健康危険情報

特記すべき事項なし。

G．研究発表

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H．知的財産権の出願・登録状況

現時点ではなし。

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労災疾病臨床研究事業費補助金
分担研究報告書

抗力を具備した継手付き体幹装具による，歩行時の脳機能へ効果

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研究要旨
腰痛は労災疾病対策の重要課題であり，その背後には不良姿勢がある事が多い．近年，不良姿勢を改善するための，継手に抗力を具備する体幹装具が開発された．本装具の装着により，静止立位時や歩行時の姿勢が改善し，歩行パフォーマンスも向上することが確認されているが，神経系への影響は未だ調べられていなかった．本研究では健常者を対象に，抗力付き体幹装具装着による，歩行時の高次運動野の活動への影響を検討した．結果，歩行安定期に補足運動野の活動は装着下でより早期に低下し，運動前野の活動は装着下でより晩期に低下した．抗力付き体幹装具の装着により，垂直姿勢の維持や運動制御に関わる高次運動野の活動が修飾されたと考える．

A．研究目的

厚生労働省が公表する業務上疾病発生状況等調査によると，休業 4 日以上の業務上疾病の発生件数のうち腰痛は，長年に渡り全職業性疾病の約 6 割を占め第 1 位であった．また，世界疾病負担研究でも腰痛が Years Lived with Disability のトップにランクされている．このように，腰痛は日本国内のみならず世界的にも頻度が高く，これによる社会的損失は大きい．腰痛は労災疾病対策の重要課題である．

腰痛の背後には，不良姿勢があることが多い．不良姿勢を矯正する旧来の体幹装具は，腹部を圧迫して固定する方式か，胸部・腰背部・恥骨部の 3 点で固定する方式であり，これらの方式を用いた体幹装具を長期間使用すると体幹筋群が弱化すると報告されている．近年，継手の抗力によって体幹を伸展方向に回転させる力と骨盤を前傾方向に回転させる力を与えて姿勢を矯正し，腹筋群の活動を促す新たな抗力を具備した継手付き体幹装具（以下抗力付き体幹装具）が開発された[1]．本装具の装着により，静止立位時や歩行時の姿勢が改善し，歩行パフォーマンスも向上することが確認されている[2-4]．

ヒトの姿勢・動作は神経系によって制御されており，大脳皮質では一次運動野のみならず，補足運動野や運動前野などの高次運動野も関与している[5,6]．抗力付き体幹装具の装着で姿勢・動作が変化した際には，これらの皮質の活動も変化していることが予想されるが，これを示した研究は未だ無い．そこで本研究では，抗力付き体幹装具装着による，歩行時の高次運動野の活動への影響を調べた．

B．研究方法

対象を健常者 10 人とした．各人に，抗力付き体幹装具非装着と装着の 2 条件でトレッドミル歩行を行ってもらい，その際の脳活動を調べた．

脳活動の計測には，近赤外光脳機能計測装置（OEG-17APD, Spectratech 社）を用いた．プローベは運動野・補足運動野・運動前野を計測できるように３×８で配置した．各条件で，安静立位時をベースラインとし歩行時の活動を計測した．

解析は，ノイズ等で適切な信号を得られなかった２名を除き，８名で行った．

（倫理面への配慮）

実施に際し，新潟医療福祉大学倫理委員会での承認を得た．調査への参加は完全な任意であり，インフォームドコンセントの上行われた．

C．研究結果

補足運動野は，歩行安定期に，抗力付き体幹装具非装着下に比べ装着下ではより早期に有意に低下した．

左右の運動前野は，歩行安定期に，抗力付き体幹装具非装着下に比べ装着下ではより晩期に低下した．

D．考察

補足運動野は垂直姿勢の維持に関わるとされ，歩行安定期に抗力付き体幹装具装着下でより早期に有意に低下したのは，垂直姿勢が抗力付き体幹装具によって補完されたためと考える．運動前野の背側部は視覚情報による運動の空間的制御に関わるとされ，抗力付き体幹装具装着下の歩行安定期の低下がより晩期に起こったのは，姿勢の変化による視覚座標系の変更による可能性がある．

垂直姿勢を保つことができない不良姿勢は筋骨格系だけでなく，高次運動野にも影響を及ぼしている可能性がある．今後は，実際に不良姿勢を呈する人や腰痛患者を対象に計測を行っていく予定である．

E．結論

抗力付き体幹装具の装着により，垂直姿勢の維

持や運動制御に関わる高次運動野の活動が修飾されたと考える.

Ｆ．健康危険情報

該当なし.

Ｇ．研究発表

1. 論文発表　なし

2. 学会発表　なし

（発表誌名巻号・頁・発行年等も記入）

Ｈ．知的財産権の出願・登録状況（予定を含む.）

1. 特許取得

該当なし

2. 実用新案登録

該当なし

3. その他

該当なし

Ｉ．参考文献

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労災疾病臨床研究事業費補助金

分担研究報告書

介護看護従事者への予防介入とマネジメントシステムの構築に関する研究

-労災病院に勤務する看護師に対する腰痛予防の大規模介入研究-

研究分担者　三好光太　横浜労災病院　整形外科

研究要旨

厚生労働省調査にて、業務上疾病の発生件数は、腰痛が全職業性疾病の約 6 割を占め第 1 位であること、平成 23 年の腰痛全届け出のうち社会福祉施設で腰痛が顕著な増加を辿っていることなどから介護・看護従事者への腰痛対策は、産業衛生領域の喫緊の課題といえる。

本研究では、産業衛生領域の喫緊の課題である腰痛対策を効率的に行うために、簡易で即実践できる体操に加え、産業理学療法士からの科学的根拠に基づいた教育の有益性に大規模介入比較試験を施行した。

具体的には、全国 12 労災病院をクラスターとして、A:対照（無介入）、B：腰椎伸展体操の普及・実践、C:B+産業理学療法士による腰痛教育・相談の実践の 3 群の無作為比較試験を行った。研究最終年度となる本年度は、6 か月後の追跡調査を行った。各群の回収数は A 群 949 名、B 群 706 名、C 群 751 名、計 2,406 名であり、追跡率はそれぞれ 71.9%、70.6%、67.0%で、全体では 70.0%あった。

腰痛と関連情報を把握するためのアンケート調査を行った結果、腰痛の自覚症状改善の割合は,A 群で 13.3%、B 群で 23.5%、C 群で 22.6%と介入群で上昇していた。また腰痛予防対策の実行度はコントロール群で低くなっていた。

A. 研究目的

厚生労働省業務上疾病発生状況等調査にて、腰痛における休業 4 日以上の業務上疾病の発生件数は、全職業性疾病の約 6 割を占め第 1 位となっている。平成 23 年の腰痛全届け出のうち社会福祉施設が 19%を占め、10 年で 2.7 倍という最も顕著な増加となった背景を踏まえ、19 年ぶりに改訂された「職場における腰痛予防対策指針」(平成 25 年、厚生労働省)では、重症心身障害児施設等に限定されていた適用を、福祉・医療等における介護・看護作業全般に拡大し、内容を充実させるに至った。つまり、介護・看護従事者への腰痛対策は、産業衛生領域の喫緊の課題といえる。また世界疾病負担研究にて 289 の疾患や傷病のうち､腰痛が Years Lived with Disability (YLDs)のトップにランクされるなど、社会的損失や健康面への影響の大きい腰痛への対策は global にも重要な課題として位置づけられている。

また疾患の対策としては、高リスク群のみに限定して対策を行うハイリスク・アプローチは、高リスクと考えられなかった大多数集団が潜在的なリスクを抱えたていた場合、効果的な手法とは言

えない。このため対象を一部に限定せずに集団全体へアプローチをし、全体としてリスクを下げ集団としての健康状態を向上させるポピュレーションアプローチが注目を集めている。

本研究では、産業衛生領域の喫緊の課題である腰痛対策を効率的に行うために、簡易で即実践できる体操に加え、産業理学療法士からの科学的根拠に基づいた教育の有益性をポピュレーションアプローチに基づいた大規模介入比較試験で検討することにより、エビデンスを構築する。研究 3 年目となる本年度は、介入後に 6 か月の期間をおき、腰痛と関連情報を把握するためのアンケート調査を行った。

B. 研究方法

全国 12 労災病院をクラスターとして、A:対照（無介入）、B：腰椎伸展体操の普及・実践、C:B+産業理学療法士による腰痛教育・相談の実践の 3 群を実施するため、統計学的な見地を踏まえデザインを行い、介入を実施し追跡調査が終了した。

（論理面への配慮）

本研究は、研究対象者の組み入れ前であるが、同意取得やデータは匿名化の方法は確立しており、研究遂行にあたり倫理面での問題はないとの承認を、全国労災病院倫理委員会より得ている。

C. 研究結果

以下の研究プロトコールの通りに、ベースライン調査を実施した。

①施設をクラスターとした無作為比較試験

選択基準:選定された労災病院に勤務する成人（20 歳以上）看護師、本研究の趣旨に賛同し同意を得た者

除外基準：妊婦，あるいは妊娠の疑いがある場合、腰椎伸展により症状が誘発される腰部脊柱管狭窄症と診断されたことがある者、研究の同意を撤回した者

②対照（無介入）、腰椎伸展体操の普及・実践、B の介入+産業理学療法士による腰痛教育･相談の実践の 3 群

③北海道中央（看護師数：156）、東北（407）、関東（562）、横浜（667）、新潟（274）、浜松（256）、旭（182）、大阪（720）、関西（674）、中国（391）、愛媛（193）、長崎（285）、総計 4,767 名。以上 12 労災病院（施設）のをクラスターとし、病床・看護師数、看護師の男女数・平均年齢を割付調整因子とし、コンピューターの乱数表を用い、3 群（4 施設ごと）に無作為割付する非盲検試験を行った。

④A 群は北海道中央、横浜、大阪、浜松の 1,799 名、B 群は関東、旭、中国、長崎の 1,420 名、C 群は東北、新潟、関西、愛媛の 1,548 名、全体で 4,767 名にアンケートを配布した。全体でのアンケート回収数は 3,439 名分で、回収率は 72.1%だった。各群の回収数は A 群 1,319 名、B 群 1,000 名、C 群 1,120 名であり、回収率はそれぞれ 73.3%、70.4%、72.4%であった。

回収したアンケートのうち 58 名に不備があったためベースライン解析には 3,381 名分のアンケートを利用した(A 群 1,292 名、B 群 987 名、C 群 1,102 名)。

ベースライン調査での各群の背景情報は以下のとおりである：

	A 群	B 群	C 群
年齢	35.5 (35.0-36.1)	35.1 (34.5-35.8)	35.5 (34.9-36.1)
性 男性（%）	6.7	5.3	4.2
BMI	21.2 (21.0-21.3)	21.5 (21.3-21.6)	21.1 (20.9-21.3)

StarTBack high risk(%)	2.2	2.8	2.2
FABQ 15 点以上（%）	27.7	30.2	29.6
EQ5D	0.88 (0.87-0.89)	0.87 (0.86-0.88)	0.88 (0.87-0.89)

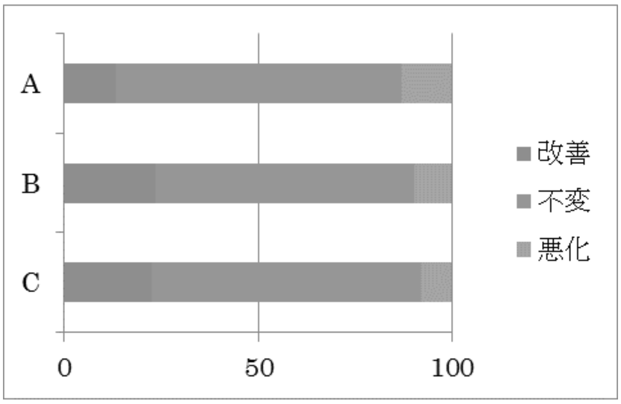
上表内の（ ）には 95%信頼区間を示した。
各群の背景情報の分布は上表に示すとおりであり、全ての群で似通った傾向であった。

⑤6 か月後の追跡調査時の、各群の回収数は A 群 949 名、B 群 706 名、C 群 751 名、計 2,406 名であり、追跡率はそれぞれ 71.9%、70.6%、67.0%で、全体では 70.0%あった。以下に追跡可能だった症例のベースライン時における各群での背景情報を記載する。

	A 群	B 群	C 群
年齢	36.8 (36.1-37.5)	36.1 (35.3-36.9)	35.1 (34.7-36.3)
性 男性（%）	7.1	6.3	6.2
BMI	21.3 (21.1-21.5)	21.6 (21.3-21.8)	21.2 (20.9-21.4)
StarTBack high risk(%)	2.0	2.1	1.9
FABQ 15 点以上-BL（%）	26.8	28.9	29.1
EQ5D-BL	0.88 (0.87-0.89)	0.87 (0.86-0.88)	0.88 (0.87-0.89)
EQ5D-6M	0.88 (0.87-0.89)	0.87 (0.86-0.88)	0.89 (0.89-0.90)

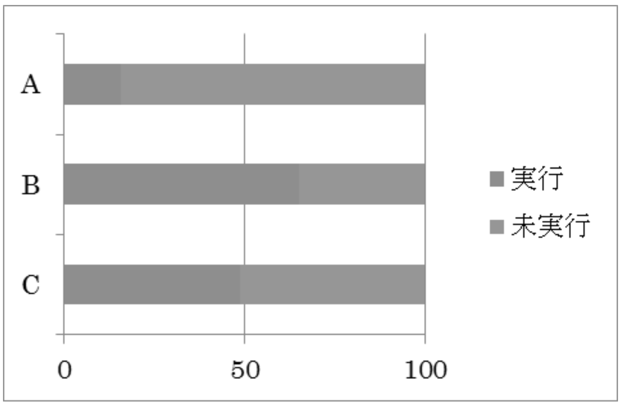
上表内の（ ）には 95%信頼区間を示した。
各群の背景情報の分布は上表に示すとおりであり、全ての群で似通った傾向であった。前述した全例でのベースライン調査での各群の背景情報追跡可能例とでは、背景情報の傾向は異ならなかった。

⑥本研究の主要評価項目は腰痛の自覚的改善度である。



各群の改善、不変、悪化の割合(%)を上図に示す。A,B,C 群での改善の割合は,13.3%、23.5%、22.6%であった。悪化の割合は 13.0%、9.6%、8.1%と介入の度合いが高いほど減少していた（Cochran-Armitage の傾向検定:P< 0.0001）。

腰痛予防対策の実行度(%)を下図に示す



A,B,C 群での実行度の割合は 15.6%、64.9%、48.8%であり A 群（コントロール群）での実行度が低くなっていた（カイ 2 乗検定：残差分析 p<0.05）。

腰痛の改善を目的変数として、背景を調整しても介入治療効果が認められるかに関して多変量解析（Logistic 回帰分析）を用いて検討した。雇用の安定等に関する法律（高年齢者雇用安定法）をもとに、45 歳以上を「中高年齢者」と、また BMI 25 以上を肥満と定義した。

	Odds 比	95%信頼区間	p 値
性（男性）	1.0	(0.7-1.7)	0.89
中高年齢者	0.9	(0.7-1.1)	0.36
肥満	0.8	(0.6-1.1)	0.10
StarTBack high risk	0.8	(0.4-1.6)	0.70
FABQ 15 点未満	1.4	(1.1-1.7)	0.01
A 群 vs. B 群	2.1	(1.6-2.7)	<0.0001
A 群 vs. C 群	2.0	(1.5-2.6)	<0.0001

多重共線性を検討するために、各説明変数の分散拡大係数:variance inflation factor (VIF) を算出した。この結果、性（男性）・中高年齢者・肥満・StarTBack high risk・FABQ15 点未満・治療 B 群・治療 C 群で、それぞれ 1.0、1.0、1.0、2.1、1.1、1.3、1.3 でいずれも 10 を超えておらず、説明変数間に多重共線性は生じていないものと判定した。

多変量を調整した Logistic 回帰分析の結果、B の介入（腰椎伸展体操の普及・実践）、C の介入（B の介入+産業理学療法士による腰痛教育・相談の実践）とも有意に腰痛を改善（コントロール群の約 2 倍）することが分かった。また FABQ が 15 点未満であることは腰痛改善の因子であることが明らかになった。

D. 考察

産業衛生領域の喫緊の課題である腰痛対策を効率的に行うために、簡易で即実践できる体操に加え、産業理学療法士からの科学的根拠に基づいた教育の有益性を検証するために大規模介入比較試験を施行した。研究３年目となる本年度は、統計学的な検討に基づいた割付を行い、6 か月の期間をおき、腰痛と関連情報を把握するためのアンケート調査を行った。この結果、腰痛の自覚症状改善の割合は,コントロール群で 13.3%、腰椎伸展体操の普及・実践群で 23.5%、+産業理学療法士による腰痛教育・相談の実践 22.6%と、いずれの介入によっても上昇していた。

また腰痛予防対策の実行度はコントロール群で低くなっていた。多変量を調整した Logistic 回帰分析の結果、介両介入群とも有意に腰痛を改善（コントロール群の約 2 倍）することが分かった。また FABQ が 15 点未満であることは腰痛改善の因子であることが明らかになった。

E. 結論

ポピュレーションアプローチに基づいた介入研究を行い、介入群で腰痛の自覚的改善度、腰痛予防対策の実行度が高くなっていることが明らかになった。

F. 健康危険情報

該当なし

G. 研究発表

1. 論文発表

現時点でなし

2. 学会発表

現時点でなし

H. 知的財産権の出願・登録状況（予定を含む）

特許取得　実用新案登録

現時点でなし

労災疾病臨床研究事業費補助金

分担研究報告書

個人と職場の双方に有益な腰痛治療と職業生活との両立支援手法の開発 -腰痛予防への効率的かつ効果的な理学療法介入に関する研究-

研究分担者

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研究要旨

平成 28 年度においては，まず，メール指導を効率的かつ効果的に行うことを目指して開発した産業理学療法指導システム「Consulting system for physical therapy in occupational health: Compo」を用いた介護職員を対象としたメール指導の効果検証を無作為化比較デザインで行った．中間解析の結果，メール指導に対する介護職員の満足度は比較的高かったが，メール指導後の腰痛の程度や心理社会的要因に介入群と対照群の間で有意な差は認めなかった．ついで，諸外国の情報をふまえ，日本の理学療法士が腰痛予防へ関わっていく上での現状と課題を分析した．結果，養成教育（人材育成）およびエビデンス構築の 2 点が課題であり，これらを充実させて腰痛予防における理学療法士活用の有用性を社会に発信することが重要と考えられた．最後に，腰痛予防の重要性を広く認知してもらうために，これまでに作製した腰痛予防の教育教材をインターネットや SNS を利用して普及啓発を行い，さらにこれらをどのように活用していけばよいか検討した．

A. 研究目的

平成 26 年度には我々が過去に行った事務系職員 20 名を対象とした理学療法士による腰痛予防を目的としたメール指導の現状と問題点を分析した [1]．理学療法士によるメール指導に一定の効果を認めるが，多数の労働者を対象にする場合には，簡便に使用可能で，かつ多数のデータを管理するためのデータベース・システムの構築が必要と考え，平成 27 年度にはメール指導を効率的かつ効果的に行うためのシステムとして，産業理学療法システム「Consulting system for physical therapy in occupational health: Compo」の開発を行った [2]．また，腰痛予防に対する理学療法の情報を国内外から収集，腰痛予防の重要性や具体的な予防方法を普及啓発させることを目的として腰痛予防のための教育教材の作製を行った．

平成 28 年度においては，まず，Compo を用いたメール指導の効果検証について介護職員を対象とし，無作為化比較デザインで行うことを目的とした．ついで，諸外国の情報をふまえ，日本の理学療法士が腰痛予防へ関わる上での現状と課題を分析することを目的とした．最後に，腰痛予防の重要性を広く認知してもらうために，これまでに作製した腰痛予防の教育教材をインターネットや SNS を利用して普及啓発を行い，さらにこれらをどのように活用していけばよいか検討することを目的とした．

B. 研究方法

1）Compo を用いたメール指導の効果検証

1. Compo の機能概要

Compo はパソコン, スマートフォンおよびフィーチャーフォンで利用可能である [2]．利用者の登録ならびに権限の変更などのシステム設定は，システム管理者として産業理学療法研究会が担当する．システム管理者からは，個別ならびに一斉連絡やアンケート調査を指導者となる理学療法士，相談者となる対象者は，仮名で登録され，相互に個人情報が公開されることはない．指導者および相談者は，Compo を通して相互にメッセージを送受信することができ，また，画像の添付も可能である．Compo にメールアドレスを登録することによって，メッセージの着信も即座に可能となる．

2. 対象者と指導者

研究の対象者は 30 歳から 65 歳までの介護施設で勤務する介護職員である．選択基準は，過去に腰痛を経験する者および腰痛の不安をかかえている者，携帯電話もしくはパソコンを持ち，これらを使うことができる者とした．除外基準は，急性腰痛を有し治療中の者，精神疾患を有し治療中の者，上下肢の重篤な運動機能障害を有する者，そのほか研究者が対象者として不適当と判断した者とした．

指導者は，3 年以上の経験を有する理学療法士であり，（一社）産業理学療法研究会の会員である．指導者は，研究会のメーリングリストを用いて募集し，研究の趣旨を説明の上，同意を得た．システム利用方法ならびに指導方法のマニュアルを作成し，メール指導の標準化を行った．また，指導者には，日常業務として労働者の腰痛予防に従事し, 20 年以上の臨床経験を有する理学療法士がスーパーバイザーを務めた．

3. 研究の実施手順

国内の 11 施設の協力を得た．対象者には口頭と紙面で説明の上，書面で同意を得た．同意を得た対象者は登録センター（関西福祉科学大学）にて，無作為にメール指導を行う群（介入群）および対照群（メール指導を行わない群）の 2 群に振り分けた．介入・観察期間は 6 カ月である．まず，指導者から対象者へメールを送信し，以降，1 カ月に 1 回，指導者から対象者へメールを送信することを原則とした（計 7 回）．指導者は対象者からの相談に対して個別に対応することとした．尚，対照群についても観察期間終了後，介入群と同様に指導を行うこととした．

4. 測定項目と解析方法

対象者の一般特性として, 性別, 年齢, 身長, 体重，喫煙の有無，介護業務の経験年数，管理職の有無，夜勤の有無，1 週間当たりの労働時間などのデータ収集を行った．また，介入あるいは観察前後で，ここ 4 週間の腰痛の程度を 0（まったく痛みのない状態）-10（想像しうる最悪の痛み）点法の Visual Analog Scale（VAS），ここ 30 日の仕事の出来を 0（最低）-10（最高）点法，抑うつの状態を K6 質問票日本版，心理社会的要因を Subgrouping for Targeted Treatment（STarT） Back スクリーニングツール日本語版，腰痛に対する恐怖回避思考を日本版 Fear-Avoidance Beliefs Quetionnaire（FABQ-J），健康関連の生活の質（health-related quality of life，HRQoL）を日本語版 EuroQoL で評価し効用値を算出した．さらに，介入群では，介入終了後に，理学療法士によるメール相談によって腰痛予防の効果があると感じたか，理学療法士によるメール相談の満足度についてなどの聴取を行った．

解析方法について，一般特性はカイ2乗検定および対応のないt検定で2群の比較を行った．介入あるいは観察前後の比較において，群内比較には対応のあるt検定を使用した．さらに前後の変化量を用いて，対応のないt検定により群間比較を行った．統計解析ソフトはIBM SPSS Statics 22を用い，有意水準は5%とした．

5. 研究倫理と臨床試験登録

本研究は関西福祉科学大学研究倫理委員会の承認を受けた（承認番号 14-32）．本研究はUMIN-CTR（UMIN000018450）に臨床試験登録した（課題名「産業理学療法指導システム（Compo）による勤労者の腰痛予防効果の検証」）．

2) 理学療法士が腰痛予防へ関わる上での現状と課題

平成28年度においては，これまでの成果をリバプールで開催された第4回欧州理学療法学会（ER-WCPT 2017）で発表し意見交換を行うなど，引き続き諸外国からの情報を収集することとした．

諸外国から収集した情報をふまえ，まず，日本における一般的な理学療法・理学療法士の役割（病院や介護保険施設などの臨床の理学療法業務）と腰痛予防への理学療法・理学療法士の役割（産業保健分野における理学療法業務）を明確に区別化することとした．ついで，理学療法士養成教育（人材育成）について，日本との比較を行うこととした．エビデンス構築については，理学療法士の職域拡大の視点からも検討を行うこととした．

表1. 対象の一般特性

	介入群	対照群	P値
男女(n)	7 / 6	4 / 6	NS
年齢(歳)	45±9	44±7	NS
身長(cm)	164±8	163±11	NS
体重(kg)	63±14	62±13	NS
喫煙者(n)	1	1	NS
経験年数(n)			
5年未満	5	5	NS
管理職(n)	2	3	NS
夜勤の有無(n)			
有り	7	7	NS
1週間の労働時間(n)			
40時間未満	2	1	NS

NS, not significant.

表 2. 介入群および対照群における前後の比較と 2 群の変化量の比較

	介入群				対照群				変化量のＰ値
	前	後	Ｐ値	変化量	前	後	Ｐ値	変化量	
ここ 4 週間の腰痛の程度	2.31 (2.01)	2.31 (2.42)	NS	0.01 (2.67)	1.80 (2.15)	1.90 (2.55)	NS	0.10 (0.73)	NS
ここ 30 日の仕事の出来	6.31 (1.43)	6.23 (1.23)	NS	-0.07 (1.89)	5.30 (2.58)	4.30 (2.98)	NS	-1.00 (2.82)	NS
K6	2.15 (1.67)	2.62 (2.87)	NS	0.46 (1.71)	3.10 (3.17)	4.30 (5.55)	NS	1.20 (2.78)	NS
STarT Back（総合得点）	1.23 (1.42)	1.69 (1.97)	NS	0.46 (1.50)	1.40 (2.17)	1.30 (2.00)	NS	-0.10 (0.99)	NS
STarT Back（領域得点）	0.77 (0.92)	1.08 (1.49)	NS	0.30 (1.25)	0.80 (1.31)	0.70 (1.05)	NS	-0.10 (0.56)	NS
FABQ-J	8.31 (6.95)	8.62 (5.51)	NS	0.30 (4,23)	10.80 (9.02)	8.10 (6.50)	NS	-2.70 (8.65)	NS
HRQoL（効用値）	0.91 (0.11)	0.82 (0.24)	NS	-0.09 (0.23)	0.87 (0.15)	0.84 (0.19)	NS	-0.03 (0.17)	NS

平均値(標準偏差). NS, not significant.

表 3. 介入群における介入終了後の感想

回答	n
理学療法士によるメール相談によって腰痛予防の効果があると感じたか	
効果があった	5
あまり効果はなかった	5
まったく効果がなかった	1
未回答	2
理学療法士によるメール相談の満足度について	
かなり満足である	1
満足である	7
不満がある	2
未回答	3

3）開発した腰痛予防教育教材の普及啓発

我々は，平成 27 年度に腰痛予防を目的とした 2 つの教育教材を開発した．1 つ目は，腰痛予防を目的とした看護師を主な対象としたスクリーンセイバーである（スライド枚数・全 5 枚）．2 つ目は，動画であり，「腰痛予防に関する基礎的な知識」，「腰痛予防のための運動」，「様々な状況を想定し腰痛発生の予防を目指したトランスファー技術」の 3 部構成である．これら開発した教育教材を普及させるために，ソーシャルネットワーク等を利用して情報発信することとした．

C. 研究結果

1）Compo を用いたメール指導の効果検証

表 1 には対象者の一般特性を示す．介入群および対照群において，全ての項目に有意な差は認めなかった．表 2 には各群における前後の比較と 2 群の変化量の比較を示す．各群において，前後の全ての項目に有意な差は認めなかった．

また，2 群間の変化量についても全ての項目に有意な差を認めなかった．表 3 には，介入群における介入終了後の感想を示す．理学療法士によるメール相談によって腰痛予防の効果があると感じたかについての質問において，「あまり効果がなかった」，「まったく効果がなかった」と回答した 6 名およびメール相談の満足度について，「不満がある」と回答した 2 名の自由記載の意見に関して代表的な内容を以下に示す：腰痛自体は軽い方だが，一度仕事中にぎっくり腰になった際，具体的な対処方法などの指導はなく腰痛防止には役立っていなかった；現在のところ痛みがない為，相談らしい相談を行うことができなかった；メールのやり取りがスムーズでなく，確認の頻度が減っていった．

2）理学療法士が腰痛予防へ関わる上での現状と課題

諸外国の情報をふまえ，日本における一般的な臨床の理学療法（臨床理学療法）と腰痛予防を中心とした産業保健分野における理学療法（産業理学療法）の違いについて，表 4 に示した．

理学療法士による対象者への関わりについて，日本では対象者（患者）が理学療法を受けるには医師の処方が必要である．一方，英国では 1978 年から医師の処方箋がなくとも理学療法士が必要と判断して行う治療も国民保健サービスでカバーされ，開業の有無や届出等も関係するが対象者による理学療法士へのダイレクトアクセスが可能である国がある [3)]．

理学療法士の教育制度について，米国では大学卒業後に約 3 年をかけての大学院教育，豪国では 4 年制の大学教育で行われるなど一定に統制された高等教育で理学療法士養成を行っている国がある一方，日本では 3 年制および 4 年制の大学・専門学校混合教育で理学療法士の養成が行われている．例えば University of South Australia の理学療法学科では 4 年次に講義・現場での実習を含め，多くの時間をかけて「産業保健と安全管理（occupational health and safety）」について教授されるが [4)]，日本では，産業保健分野の理学療法に関しては，ほぼ全ての養成校で教育されていないのが現状である．

理学療法士が行うことのできる業務範囲については開業権が認められている国や消炎鎮痛薬の処方が認められる国があるなど，各国で異なるのが実情である [3)]．

3）開発した腰痛予防教育教材の普及啓発

スクリーンセイバーについては，（一社）産業理学療法研究会の会員に無料で提供することとし，自らの職場や研究フィールでの活用を促した．さらに，スクリーンセイバーについては，問い合わせのあった場合には無償提供しており，今後は研究会のホームページを通して会員以外にも無料で提供する予定である．動画については，3 部構成の一部である「様々な状況を想定し腰痛発生の予防を目指したトランスファー技術」の一部について，YouTube で公開した．今後，更なる動画の普及を計画している．

一方，腰痛予防を目的とした教育教材を開発し，無料で，かつ全国的に利用できるようにインターネットや SNS を活用して普及啓発して

表 4. 臨床の理学療法と産業保健分野における理学療法の違い（私案）

	臨床理学療法	産業理学療法
主な実施場所	病院，診療所や介護保険施設	職　場
目　的	障がい・疾病の改善	生産性の向上
対　象	本人（家族）	職場全体（上司や同僚含む）
対象の動機	機能・能力の改善	必ずしも同期を持たない
経済的背景	健康保険 / 自己負担	事業者責任（企業活動の一部）
対象による選択	医療機関・医師の選択は自由	基本的に選択できない
理学療法介入	本人および家族	本人および組織

いるが，指導者となる会員などからは，教育教材を用いて，どのように労働者へ教育すれば効果的なのか，教育教材の活用方法に関する研修会が必要との意見が多数認められた．

D. 考察

1） Compoを用いたメール指導の効果検証

我々は，以前に事務系勤労者を対象として，腰痛予防を目的とした理学療法士によるメール指導の効果を検証した[1]．結果，6カ月後にWork Ability Indexの有意な向上，FABQの改善傾向を認め，理学療法士によるメール指導に一定の効果を認めることを明らかにした．

平成28年度においては，より効果的・効率的なメール指導が行うことを目的として開発したCompoを用い，腰痛の発生が多い業種である介護職員を対象にして，メール指導の効果を検証した．介入群13名，対照群10名を研究対象とした中間解析の結果，メール指導の有効性は有意差として認められなかった．現在の分析は中間解析の結果であり，対象数が増えれば結果が異なる可能性があるが，現状の分析においても効果を認めない，あるいは効果が表れにくい対象がいることは確実と考えられる．どのような業種，どのような身体的・心理社会的要因を有する対象，またその他要因を有する対象者にメール指導の効果があるのかを検証することは，メール指導の対象となるターゲットを明確にするためにも重要であり，今後の研究課題である．

2） 理学療法士が腰痛予防へ関わる上での現状と課題

理学療法の社会的地位が高い欧米諸国において，4年間の教育で理学療法士免許が授与される国がある中で，日本も修業年限だけは3～4年間であるので，何をもって教育内容が充実，レベルの違いがあるかについては諸外国と日本との単純比較は難しい．歴史的背景，法制度をふまえて，日本の理学療法士の卒前教育において産業理学療法が教授されてこなかったことについては不適切とは言及できないが，日本の理学療法士が産業保健分野で活躍するためには，産業理学療法に関する教育が必要不可欠である．コアカリキュラムが設定される卒前教育において，新たな産業理学療法のカリキュラムを設定して，それに多くの時間を費やすのは現状では難しいため，卒後教育において産業理学療法に関する教育内容をいかに充実させていくかが課題と考える[4]．

エビデンスの構築にあたっては，労働者を雇用する側および保険組合へ如何に理学療法の必要性や有効性，理学療法士が関わることでのメリットを示していくかが重要であると考える．例えば，雇用する側と保険組合に対しては，某企業において理学療法士が関わることにより，労働力の損失を防止，勤労者の生産性の向上に寄与することができるかを示せれば雇用する側にとって有用であるし，加えて医療費の削減効果を示すことができれば保険組合としても有用である．これらの観点をふまえて，理学療法のエビデンスを構築していくことができれば，産業保健分野での理学療法士の活躍の場は広がると考えられる[4]．

3） 開発した腰痛予防教育教材の普及啓発

腰痛予防を目的とした教育教材を開発し，これらをインターネットやSNSを利用して普及啓発した．今後は，これらの効果的な使い方（労働者への教育方法や労働環境への導入方法など）を検討し，人的手段あるいはインターネットによる教育教材を使用する側（指導者側）の教育も継続しなければならないと考えている．

E. 結論

1. 理学療法士による腰痛予防を目的としたメール指導は，対象者の満足度が比較的高い.
2. 理学療法士が腰痛予防を目的としたメール指導を行えば，どのような業種，どのような対象にでも効果を認めるとは言えない.
3. メール指導に効果のある業種やターゲット層を明確にする必要があり，検証される必要がある.
4. 法制度上，理学療法士養成のカリキュラムにおいて，日本と諸外国では違いがあり，腰痛予防を目的とする介入を行うには卒前教育だけでは不十分である.
5. 日本の理学療法士が腰痛予防に関わるためには卒後教育の充実化が必要であり，エビデンスの構築と共に社会に発信することが重要である.
6. 腰痛予防を目的した教育教材を普及啓発させるにはインターネットや SNS を利用することが効果的である.
7. 一方で，開発した教育教材を労働者に適応，現場へ効果的に導入するには，指導者側への教育も必要と考えられた.

F. 研究発表

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なし

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G. 知的財産権の出願・登録状況

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   なし
2. 実用新案登録
   なし
3. その他
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Ⅲ. 研究成果の刊行に関する一覧

研究成果の刊行に関する一覧表
【H28.4.1～H29.3.31】

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Ⅳ. 研究成果の刊行物・別刷

Clinical Interventions in Aging

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ORIGINAL RESEARCH

Efficacy of a trunk orthosis with joints providing resistive force on low back load during level walking in elderly persons

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Purpose: The effects of lumbosacral and spinal orthoses on low back pain and gait are not exactly clear. We previously developed a trunk orthosis with joints providing resistive force on low back load to decrease such load, and confirmed its positive effects during level walking in healthy young adults. Therefore, we aimed to determine the efficacy of this trunk orthosis during level walking in healthy elderly subjects.

Methods: Fifteen community-dwelling elderly subjects performed level walking at a self-selected speed without an orthosis, with our orthosis, and with a lumbosacral orthosis. Kinematic and kinetic data were recorded using a three-dimensional motion analysis system, and erector spinae activity was recorded by electromyography.

Results: When comparing the three conditions, our orthosis showed the following effects: it decreased the peak extension moment, increased the peak flexion moment, decreased the lateral bending angle, increased the peak thoracic extension angle, and had significantly lower erector spinae activity and significantly larger peak pelvic forward tilt angles.

Conclusion: Our orthosis with joints providing resistive force decreased low back load and modified trunk and pelvis alignments during level walking in healthy elderly people.

Keywords: biomechanics, orthosis, gait, low back pain, joint moment, motion analysis

Background

The lifetime prevalence of low back pain (LBP) is high; 70% of adults have had LBP at some time.[1] Moreover, the number of patients with LBP in developed countries is increasing in line with the proportion of elderly.[2,3]

Conservative and postoperative treatments for LBP include the use of class 1 medical devices such as a lumbosacral orthosis (LSO).[4] Cholewicki et al observed that one of the causes of LBP is excessive erector spinae muscle activity, which could be reduced with an LSO.[5] Any decrease in the compressive force exerted on the vertebral body by reducing such activity with an LSO would benefit those with osteoporosis and vertebral compression fracture, conditions to which elderly people are vulnerable.

However, a review of data held in the Cochrane Database found no evidence for the efficacy of lumbar supports alone in preventing and treating LBP.[6] Although Pfeifer et al reported that their newly designed spinal orthosis had several positive effects on muscle strength, body balance, kyphosis angle, and vital capacity in elderly patients with osteoporosis,[7] to our knowledge, no previous studies have reported any significant effects of wearing a trunk orthosis to specifically decrease erector spinae activity and low back load in elderly people. To address this issue, we previously designed a trunk orthosis to improve trunk and pelvic stability and alignment by means of resistive force

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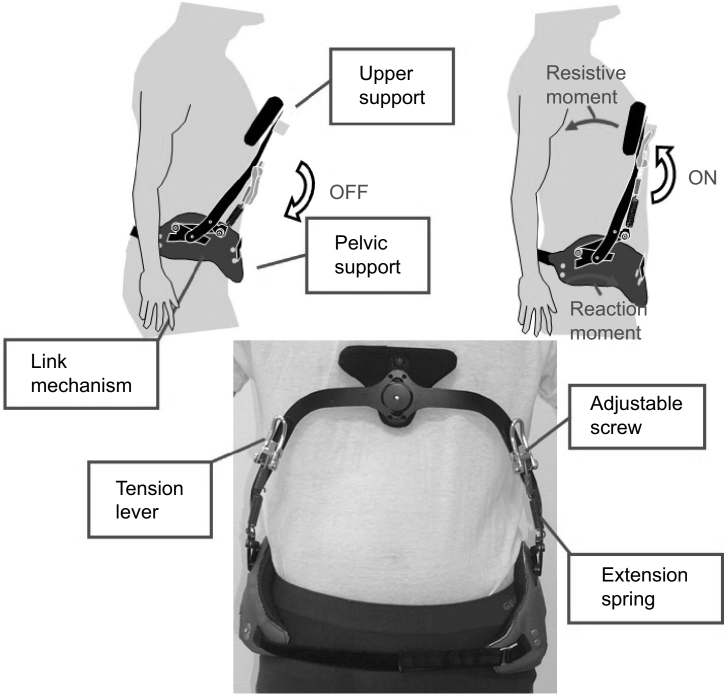

Figure 1 Our trunk orthosis with joints providing resistive force.

provided by joints with springs (Figure 1).[8] This orthosis with joints providing resistive force (ORF) creates resistive force to produce a resistive moment that rotates the trunk backward and pelvis forward. In our previous study, we reported the effect of this ORF in modifying trunk alignment and decreasing activity of the erector spinae during static standing in elderly subjects.[9]

A previous study reported that an LSO was effective for decreasing erector spinae activity in an unstable sitting position, where adjustment was needed to balance the upper body,[5] while another study showed no positive effects of an LSO on decreasing low back load by decreasing low back muscle activity and increasing intra-abdominal pressure.[10] To date, there have been no studies on the efficacy of a typical LSO or spinal orthosis for reducing low back load during level walking, where the demands for adjusting balance are high. We previously reported that our ORF prototype increased superficial abdominal muscle activity and decreased erector spinae activity during level walking in healthy young adults,[11] and here we sought to explore whether our findings can be extended to the trunk muscular activities and the low back joint moment (LBM) during level walking in healthy elderly subjects.

This biomechanics study examined the effects of the ORF on the gait of healthy elderly people during level walking and compared the effects with those obtained without an orthosis and with an LSO. We hypothesized that the ORF and LSO would both effectively decrease low back load measured by joint moment and trunk muscular activities during level walking, but that the ORF, with its biomechanical function of decreasing low back load, would show a superior effect. This follow-up to our previous study[9] was performed to confirm the hypothesis that ORF might decrease low back load not only in static standing but also in level walking, using a new biomechanical method.

Materials and methods

Subjects

From 31 community-dwelling elderly subjects who were candidates for this study, 15 were enrolled (all males; mean age, 67.7±6.1 years; mean height, 162.4±5.7 cm; mean weight, 62.3±7.8 kg) after excluding those with neurological disease, pain, history of an orthopedic surgical procedure, history of orthopedic treatment within the past 5 years, and history of LBP within the past 1 year. The study subjects were the same as those of our previous study.[9] The study was approved by the ethics committee of the International University of Health and Welfare (11–191). All the subjects provided written informed consent to participate.

Features of the ORF

The ORF is shown in Figure 1 and its features are described in our previous study.[8] Briefly, pelvic and upper supports are positioned on the ileum and sternum, respectively. Stainless steel joints, connected to the upper support with a nylon pad and to the pelvic support, produce resistive force through the use of extension springs. A link mechanism translates the spring-generated tension into a resistive moment on the chest and a reaction moment on the posterior pelvis. The ORF weighs 0.99 kg and has a range of motion of 40 degrees. The upper support initially inclines backward to exert resistive force on the chest. The ORF has a release mechanism that releases the resistive force by pulling tension levers downward. Adjustment screws control the magnitude of the spring-generated resistive force. The ORF is currently an investigational product that has not been approved by the Food and Drug Administration or by a corresponding national agency for the indication described herein.

Experimental conditions

The subjects walked 10 m on a level surface at a self-selected speed in a laboratory setting under three conditions: without an orthosis, with the ORF, and with an LSO (Damen Corset, Pacific Supply, Osaka, Japan). The Damen corset was selected as it is frequently prescribed for patients with LBP. After completing three walking trials without any orthosis, they completed three trials in the two orthosis conditions in a randomized order. A minimum rest interval of 5 minutes was set between the conditions.

The subjects were allowed 5 minutes to accustom themselves to wearing the ORF and the LSO. They then practiced level walking in the laboratory before measurements were taken. Resistive force on the chest provided by the joints was measured in real time using a strain gauge (Kyowa, Tokyo, Japan) and the force data were transferred to a laptop computer by Bluetooth (Figure 2) and the force was set to a magnitude of 20–25 N during static standing. The pressure between the corset and abdomen was set to 10 mmHg in all measurement conditions.[12]

Experimental setup

Gait was recorded with a three-dimensional motion capture system (Vicon 612, Vicon, Oxford, UK) consisting of six force plates (four from AMTI, Watertown, MA, USA; and two from Kistler, Winterthur, Switzerland) and 12 infrared (IR) cameras with a sampling rate of 120 Hz. Referring to a study by Seay et al,[13] 41 IR-reflective markers (diameter, 14 mm) were attached to each subject's body. Additionally, three markers were attached over a strain gauge and on bilateral joints of the ORF. To measure muscle activity during level walking, electromyograms (EMGs) were obtained (Biometrics, Newport, UK) at a sampling rate of 1,080 Hz for bilateral erector spinae (2 cm to the side between L4–L5 vertebrae).[14] Maximum voluntary contraction was measured while one physical therapist manually applied resistant force to the midpoints of the bilateral scapulae, with the subject lying in the prone position on a bed.

Data analysis

During acquisition, we performed full-wave rectification feeding into a band pass filter (20–420 Hz) to decrease noise and used Visual 3D analytical software (C-motion, Germantown, MD, USA). The obtained EMGs were normalized using maximal voluntary contraction during isometric

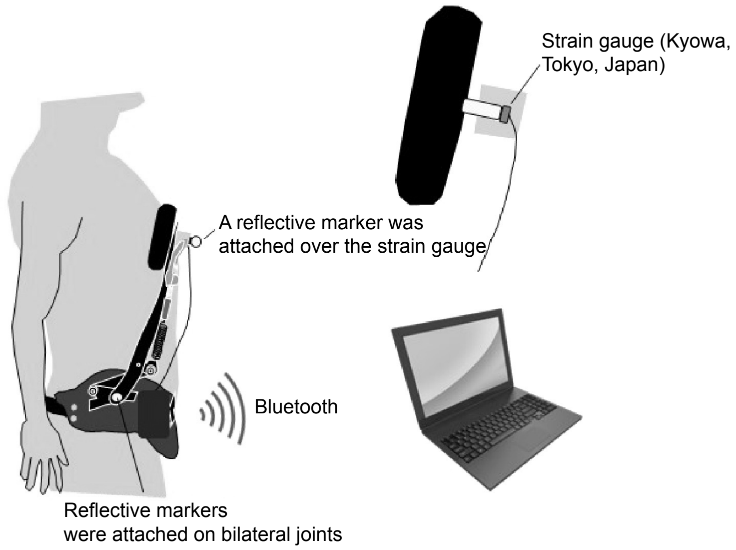

Figure 2 Trunk orthosis sensors and data transfer.

contraction (as a percent), and the root mean square was calculated for a 50 ms window. Subjects performed isometric contractions in prone against gravity with maximum resistance applied by the experimenter to obtain maximal voluntary contraction of the erector spinae.[15]

Visual 3D was used to perform kinetic and kinematic data analysis. The obtained physical coordinates and ground reaction force data were low-pass filtered with a second-order recursive Butterworth filter, with a cutoff frequency of 6 and 18 Hz, respectively, according to Winter's technique.[16] The link segment model consisted of 13 segments: head, trunk, pelvis, bilateral upper arms, forearms, thighs, shanks, and feet. Briefly, the low back extension and flexion moments were calculated using the ground reaction force data obtained from the force plates, the reaction force on the chest obtained from the strain gauge, and the coordinates of the IR-reflective markers on the bodies of the subjects and an ORF. Moment exerted by an ORF was calculated by multiplying the force measured by a strain gate and moment arm from joint of an ORF to the force. In our previous study analyzing the ORF effect during static standing,[9] we were not able to calculate LBM. The novelty of the present study lies in applying a new technique to calculate LBM during level walking while wearing an ORF. The moment was subtracted from the LBM calculated by using the ground reaction force data and the coordinates of the IR-reflective markers on the bodies of the subjects because the moment created by ORF joints equally gives forward rotation moment on the pelvis because of action–reaction law. In the analysis, segments were regarded as rigid and the joint moments were calculated using a link segment model in which segments were connected together at nodal points. To compute the joint moments, joints coordinate data were added to the ground reaction force data, in which the position of the center of mass, the weight portion, and the moment of inertia of each segment were used as parameters. The measurement data reported by Winter[16] were used as the body parameters necessary for calculating the LBM. Three-dimensional trunk and pelvic angles were calculated by the Eulerian method using coordinate systems as determined by markers on the trunk and pelvis, respectively. In this study, we defined LBM and bilateral erector spinae activities among these parameters as low back load because LBM and ES activities indicate the rotation force around the low back joint and the action of the low back muscles, respectively.

Statistical analysis

Peak values of kinetic and kinematic data acquired during level walking were extracted from the phase between mid-stance and terminal stance (MTS), and the pre-swing phase in one gait cycle of the right limb because it was not possible to calculate the LBM when a subject's posterior foot did not contact the force plates (Figure 3). Integral values of EMGs were calculated during stance. Mean

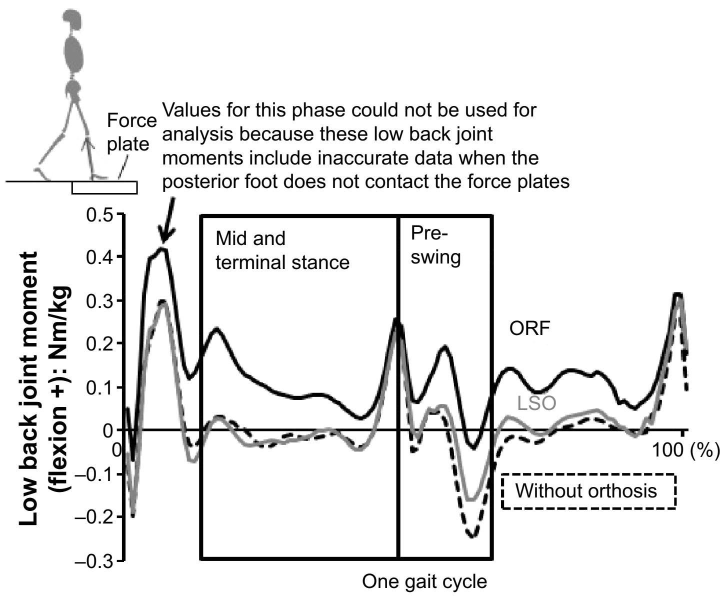

Figure 3 Average low back joint moments without orthosis (dotted line), with trunk orthosis with joints providing resistive force (ORF; solid black line), and with lumbosacral orthosis (LSO; solid gray line).

peak values of LBM, three-dimensional trunk and pelvic angles, and integral EMGs were calculated from the data obtained in three trials and were selected as representative values for analysis. Peak LBMs were normalized by subject weight (kg). Comparison was performed using repeated measures analysis of variance (ANOVA) after confirming non-deviation of the data and performing the Kolmogorov–Smirnov test, and variables showing a significant difference were subjected to multiple comparisons with Bonferroni correction. Significance was established at $P<0.05$. Statistical analysis was performed using SPSS 20 (SPSS Inc., Chicago, IL, USA).

Results

As shown in Tables 1 and 2, all kinematic and kinetic parameters differed significantly among the three conditions.

Low back load

Averaged LBM waveforms for all subjects in the three conditions are shown in Figure 3. The peak flexion moment was observed at the beginning of pre-swing and the peak extension moment at the end of pre-swing. Averaged waveforms of LBM and resistive force on the chest while wearing the ORF are shown in Figure 4. Force exerted on the chest was 34–37 N, which occurred during MTS and pre-swing. ANOVA indicated significant differences in the parameters showing low back load. Degrees of freedom for all data were 2 and 28. Significant main effects of an orthosis were observed for the peak flexion and extension moments not only in pre-swing but also in MTS (Table 1). Peak extension moments in MTS and pre-swing were significantly smaller with the ORF than in the other two conditions. The peak flexion moment in MTS was significantly larger with the ORF than with the LSO; and in pre-swing was significantly larger with the ORF than in the other two conditions.

Averaged waveforms of bilateral erector spinae activity for all subjects in the three conditions are shown in Figure 5. Peak activity was observed at the beginning of pre-swing. Significant main effects of an orthosis were observed in the integral of bilateral erector spinae activity during stance (Table 1). This integral was significantly smaller with the ORF than in the other two conditions.

Pelvic and thoracic angles

Significant main effects of an orthosis were observed in peak pelvic forward tilt angles in MTS and pre-swing, and in the peak pelvic leftward rotation angle in pre-swing (Table 2). Peak pelvic forward tilt angles in MTS and pre-swing were significantly larger with the ORF than in the other two conditions. The peak pelvic leftward rotation angle was significantly smaller with the ORF than with the LSO.

Significant main effects of an orthosis were observed in peak thoracic extension angles in MTS and pre-swing, and in peak right and left lateral flexion angles in pre-swing. Peak extension angles in MTS and pre-swing were significantly larger with the ORF than in the other two conditions. The peak right lateral bending angle in pre-swing was significantly larger with the ORF than with the LSO. The peak left

Table 1 Comparison of parameters indicating low back load in three conditions during level walking in 15 healthy elderly subjects

Parameter of low back load	Mean (95% confidence interval)			*F*-value	*P*-value from post-hoc test		
	W/O orthosis	With ORF	With LSO		W/O orthosis-with ORF	W/O orthosis-with LSO	With ORF-with LSO
Low back joint moment (Nm/kg)							
Peak extension moment in mid and terminal stance	0.19 (0.101–0.279)	0.07 (−0.019–0.159)	0.22 (0.126–0.314)	15.081***	0.002	0.777	0.002
Peak extension moment in pre-swing	0.29 (0.218–0.362)	0.11 (0.016–0.204)	0.27 (0.165–0.375)	17.658***	0.001	1.000	$P<0.001$
Peak flexion moment in mid and terminal stance	0.37 (0.254–0.486)	0.49 (0.363–0.617)	0.37 (0.259–0.481)	5.354*	0.118	1.000	0.013
Peak flexion moment in pre-swing	0.16 (0.044–0.276)	0.31 (0.188–0.432)	0.19 (0.085–0.295)	28.484***	$P<0.001$	0.337	$P<0.001$
Erector spinae activity (%IEMG)							
Integral of right side muscle activity during stance	8.22 (5.656–10.784)	7.22 (4.578–9.862)	8.21 (5.447–10.973)	7.459**	0.006	1.000	0.001
Integral of left side muscle activity during stance	10.57 (6.898–14.242)	7.32 (4.773–9.867)	9.4 (6.149–12.651)	14.917***	0.001	0.113	0.015

Notes: *$P<0.05$, **$P<0.01$, and ***$P<0.001$.
Abbreviations: LSO, lumbosacral orthosis; ORF, orthosis with joints providing restrictive force; W/O, without; IEMG, integral electromyogram.

Table 2 Pelvic and thoracic angles in three conditions during level walking in 15 healthy elderly subjects

Angle (degrees)	Mean (95% confidence interval)			*F*-value	*P*-value from post-hoc test		
	W/O orthosis	With ORF	With LSO		W/O orthosis-with ORF	W/O orthosis-with LSO	With ORF-with LSO
Pelvic angle							
Peak forward tilt angle mid and terminal stance	5.86 (3.673–8.767)	9.15 (6.431–12.789)	6.57 (4.771–8.969)	7.701**	0.011	0.841	0.071
Peak forward tilt angle in pre-swing	4.95 (2.032–7.868)	7.85 (4.195–11.505)	5.15 (2.652–7.648)	5.575**	0.040	1.000	0.064
Peak leftward rotation angle in pre-swing	3.19 (1.584–4.796)	1.75 (0.222–3.278)	3.01 (1.570–4.450)	4.473*	0.157	1.000	0.041
Thoracic angle							
Peak extension angle mid and terminal stance	1.07 (−1.007–3.147)	2.93 (0.781–5.079)	1.55 (−0.588–3.688)	16.373***	0.001	0.369	0.003
Peak extension angle in pre-swing	0.75 (−1.498–2.998)	2.80 (0.552–5.048)	1.45 (−0.826–3.726)	16.033***	0.001	0.116	0.006
Peak flexion angle in mid and terminal stance	1.15 (−0.738–3.038)	−0.71 (−2.726–1.306)	0.47 (−1.573–2.513)	12.833***	$P<0.001$	0.288	0.028
Peak flexion angle in pre-swing	0.22 (−1.918–2.358)	−1.82 (−3.93–0.29)	−0.49 (−2.639–1.659)	16.350***	0.001	0.117	0.005
Peak right lateral bending angle in pre-swing	0.64 (−0.174–1.454)	1.39 (0.465–2.315)	0.60 (−0.281–1.481)	5.548**	0.071	1.000	0.023
Peak left lateral bending angle in pre-swing	0.44 (−0.479–1.359)	−0.38 (−1.277–0.517)	0.29 (−0.591–1.171)	6.471**	0.024	1.000	0.156

Notes: *$P<0.05$, **$P<0.01$, and ***$P<0.001$.
Abbreviations: LSO, lumbosacral orthosis; ORF, orthosis with joints providing restrictive force; W/O, without.

lateral bending angle in pre-swing was significantly smaller with the ORF than in the other two conditions.

Gait performance

Walking velocity was 1.09±0.10 m/sec without an orthosis, 1.13±0.12 m/sec with the ORF, and 1.18±0.11 m/sec with the LSO. Repeated measures ANOVA showed a significant main effect (*P*=0.002). Walking velocity with the LSO was significantly faster than without an orthosis (*P*=0.017) but was not significantly different from with the ORF.

Discussion

We hypothesized that both the LSO and ORF would effectively decrease low back load during level walking in healthy

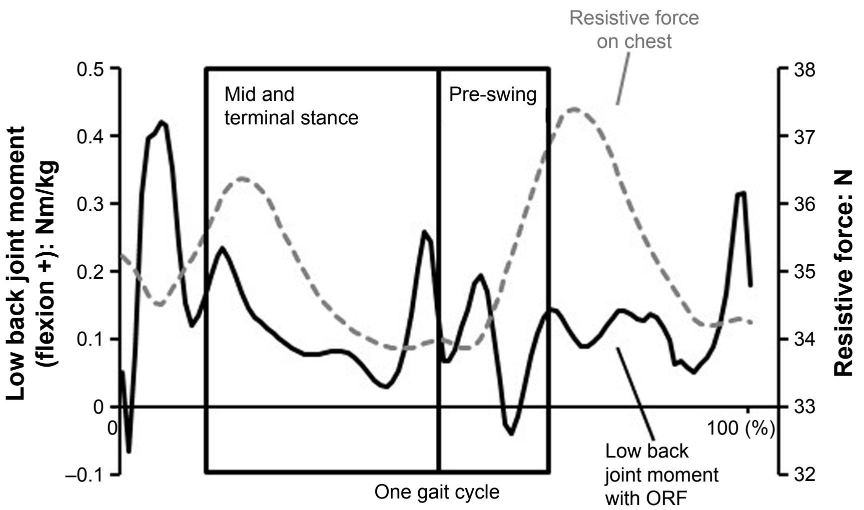

Figure 4 Average low back extension moment (solid line) and average resistive force on the chest (dotted line) with the trunk orthosis with joints providing resistive force (ORF).

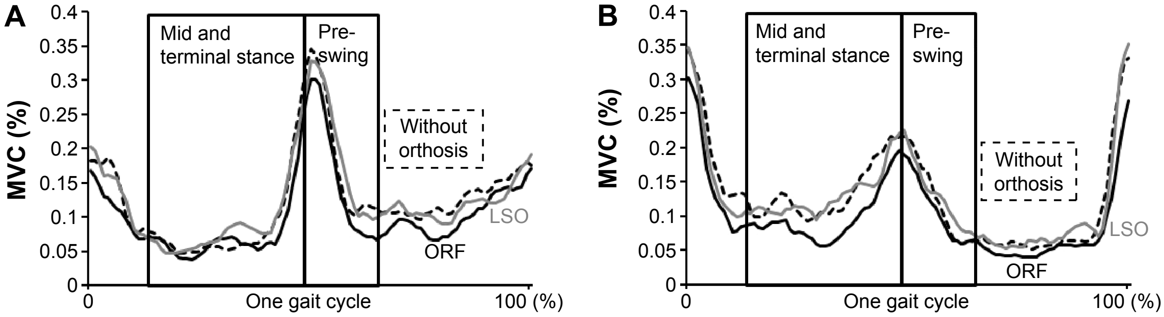

Figure 5 Right and left erector spinae activity (percent, MVC) without orthosis (dotted line), with trunk orthosis with joints providing resistive force (ORF; solid black line), and with lumbosacral orthosis (LSO; solid gray line).
Note: (**A**) Right erector spinae (**B**) Left erector spinae.
Abbreviation: MVC, maximum voluntary contraction.

elderly subjects but the ORF would have a superior effect. Our findings partially support this hypothesis. There were no significant differences between without an orthosis and with the LSO in the peak LBM and integral EMG of the erector spinae, or in the pelvic and thoracic angles. However, significant differences in all these parameters were observed with the ORF compared with no orthosis. Moreover, the low back extension moment and EMG of the erector spinae were significantly decreased with the ORF. Collectively, these results suggest that wearing the ORF during level walking should help to decrease the low back load in elderly people.

Several studies have suggested that using an LSO could stabilize the lumbosacral region but not decrease the low back load during static standing or lifting.[10] Our results indicate that the same applies during level walking also. Interestingly, the ORF not only decreased the activity of the erector spinae (which has higher fatigability in patients with LBP[17]) and the low back extension moment, but also increased the low back flexion moment created by the abdominal muscles.

The biomechanical function of the ORF can be explained by a simple model (Figure 6). The ORF can produce an extension moment for the upper trunk that decreases the low back extension moment. This extension moment also produces a resistive moment on the posterior pelvis; together, these moments could improve the malalignment commonly seen in elderly people (ie, lumbar kyphosis with pelvic backward tilt). Such malalignment increases both LBP and fall risks.[18,19] The extension moment served to extend the upper trunk, and the reaction moment acted as a forward rotation moment for the pelvis. In this way, the ORF increased the peak pelvic

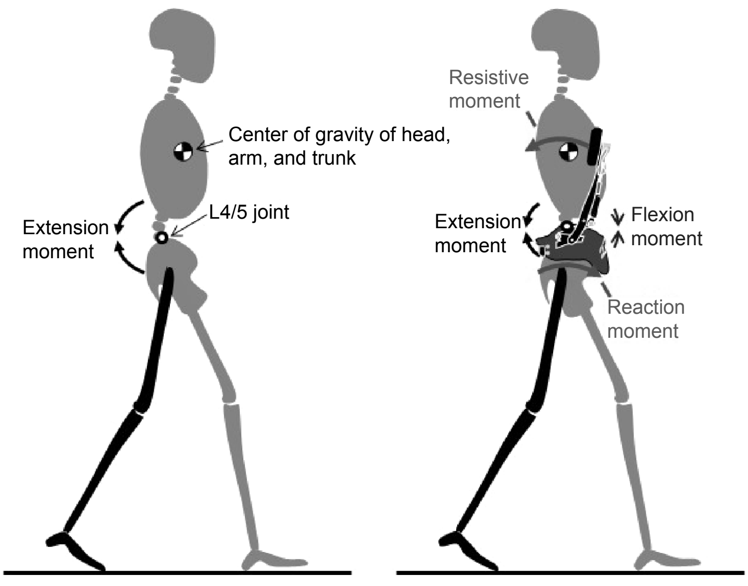

Figure 6 Biomechanical effects of the trunk orthosis with joints providing resistive force.

forward tilt angle and peak thoracic extension angle through MTS and pre-swing. This function, which can modify alignment in the elderly, would also be beneficial for decreasing the peak LBM, because modifications to the positioning of the pelvis and thorax are directly linked to a decrease in the lever arm from the low back joint to the head, arm, and trunk center of gravity (Figure 6).

A systematic review investigating the activation pattern of trunk muscles during walking in subjects with and without LBP indicated that those with LBP exhibit higher ES activity compared with asymptomatic subjects.[20] The magnitude of the decreases in erector spinae activity and the low back extension moment while wearing an ORF is relatively small. However, in daily life, people walk a large number of steps, so even though only a small decrease in low back load was evident with the ORF, the cumulative difference might have a distinct effect that can help treat and prevent LBP.[21] The spinal bones of elderly people, and particularly those of patients with osteoporosis, are more fragile than the middle-aged or young. Typical orthoses would not show a biomechanical effect of decreasing low back load during level walking because most correct only the abdominal region with compressive force or support the pelvis, thorax, and lower back with small resistive force. Only one eccentric type of orthosis, the rucksack-type orthosis, was found to decrease ES activity in elderly people during level walking in a previous study.[22] The rucksack-type orthosis controls the magnitude of force using weights to move the center of gravity of the upper body, thereby decreasing ES activity. This function is similar to that of the ORF, because both orthoses can control a relatively large magnitude of force applied to the upper trunk; however, the rucksack-type orthosis has the disadvantage of increasing low back compressive force in proportion to the amount of weight, which directly increases the gravitational force on the upper trunk. However, the ORF can apply resistive force horizontally to the chest, thereby avoiding an increase of low back compressive force.

An interesting feature of the ORF compared with other orthoses, including the rucksack-type, is its ability to increase the low back flexion moment produced by the abdominal muscles; the horizontally applied resistive force on the chest can not only decrease activity of the low back extension muscles using the support force, but also activate the abdominal muscles. The peak moment was larger with the ORF in MTS than with the LSO and in pre-swing than in the two other conditions. Rostami et al reported that using an LSO for 4 and 8 weeks decreased deep abdominal muscle thickness.[23] Although we did not examine deep abdominal muscle activity in this study, these muscles might contribute to increasing the low back flexion moment. This effect of the ORF would be beneficial for exercises aimed at improving abdominal muscle function during level walking in elderly subjects. As we previously found a positive training effect of the ORF on such function in hemiparetic patients,[8] a similar effect might be obtainable in elderly people.

A potentially negative feature of the ORF is that it limits pelvic rotation, which is one of the aspects of gait that increases step length and walking velocity.[24] Although walking velocity with the ORF was not faster than that without an orthosis, it was significantly faster with the LSO than without an orthosis. Thus, the stabilization of the pelvis and thorax achieved with an LSO might improve gait performance in elderly subjects, and the limited pelvic rotation with the ORF might decrease its overall positive effect for improving gait performance.

Limitations

This study has several limitations. Wearing the ORF during level walking served to decrease low back muscle activities and joint moment, and this might be effective in the prevention and treatment of LBP. However, we did not confirm the effects of long-term ORF use. Wearing LSOs and ORFs for long periods of time might adversely affect muscle control. Only low back extension and flexion moments in the three axial moments were calculated when wearing the ORF and therefore low back compressive force, which is a strong indicator of low back load, could not be calculated because the strain gauge measured the orthogonal resistive force on the chest produced by the ORF's joints. Finally, only healthy elderly male subjects participated in this study, and only a within-subject trial was conducted. Future studies should include healthy elderly female subjects and subjects who have LBP, and randomized controlled trials should be conducted.

Conclusion

In conclusion, we demonstrated that the ORF can decrease low back load during level walking in healthy elderly people by significantly decreasing LBM and increasing the abdominal moment. The ORF significantly modified malalignment commonly seen in elderly people. The ORF is a promising device for the prevention and treatment of LBP, and we plan to conduct randomized controlled trials with people who have LBP in the future.

Acknowledgments

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Disclosure

The authors report no conflicts of interest in this work.

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RESEARCH ARTICLE

Diagnosing Discogenic Low Back Pain Associated with Degenerative Disc Disease Using a Medical Interview

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Abstract

Purposes

To evaluate the usefulness of our original five questions in a medical interview for diagnosing discogenic low back pain (LBP), and to establish a support tool for diagnosing discogenic LBP.

Materials and Methods

The degenerative disc disease (DDD) group (n = 42) comprised patients diagnosed with discogenic LBP associated with DDD, on the basis of magnetic resonance imaging findings and response to analgesic discography (discoblock). The control group (n = 30) comprised patients with LBP due to a reason other than DDD. We selected patients from those who had been diagnosed with lumbar spinal stenosis and had undergone decompression surgery without fusion. Of them, those whose postoperative LBP was significantly decreased were included in the control group. We asked patients in both groups whether they experienced LBP after sitting too long, while standing after sitting too long, squirming in a chair after sitting too long, while washing one's face, and in the standing position with flexion. We analyzed the usefulness of our five questions for diagnosing discogenic LBP, and performed receiver operating characteristic (ROC) curve analysis to develop a diagnostic support tool.

Results

There were no significant differences in baseline characteristics, except age, between the groups. There were significant differences between the groups for all five questions. In the age-adjusted analyses, the odds ratios of LBP after sitting too long, while standing after sitting too long, squirming in a chair after sitting too long, while washing one's face, and in standing position with flexion were 10.5, 8.5, 4.0, 10.8, and 11.8, respectively. The integer scores were 11, 9, 4, 11, and 12, respectively, and the sum of the points of the five scores ranged from 0 to 47. Results of the ROC analysis were as follows: cut-off value, 31 points; area under the curve, 0.92302; sensitivity, 100%; and specificity, 71.4%.

Conclusions

All five questions were useful for diagnosing discogenic LBP. We established the scoring system as a support tool for diagnosing discogenic LBP.

Introduction

Low back pain (LBP) affects most adults at some point in their lives. In the last decade, LBP was continuously found to be the top leading cause of years lived with disability globally [1]. As in many industrialized countries, LBP is one of the most common health disabilities in Japan. In a population-based survey, the lifetime and 4-wk LBP prevalence were 83% and 36%, respectively [2].

It has been difficult to identify the cause of LBP. A specific source of pain can be identified in some cases of LBP; however, the source cannot be identified in other cases of LBP (i.e., non-specific LBP) [3]. Magnetic resonance imaging (MRI) can identify underlying pathologies of LBP. However, the importance of MRI findings is unclear and controversial. Some reports have shown that disc degeneration was a source of LBP [4,5], whereas other reports have shown that there was no relationship between disc degeneration and LBP [6,7]. Reports have also shown that discogenic LBP associated with degenerative disc disease (DDD) is confirmed by the MRI findings and response to the injection of contrast media or local anesthesia into the disc [8–10]. Schwarzer et al. reported that 39% of cases of chronic LBP are discogenic, and the diagnosis is made by computed tomography after discography [11]. The technique of injecting local anesthesia into a disc is analgesic discography (discoblock). However, these procedures do not necessarily indicate high specificity findings of discogenic LBP [12, 13], and they are invasive and harmful to the disc [14, 15].

We hypothesized that discogenic LBP is one of the causes of LBP, and we sought to determine easier and less invasive means of diagnosing discogenic LBP. Few reports have specified that LBP in the sitting position can indicate discogenic LBP [16]. However, no report has found that LBP in standing position with flexion can indicate discogenic LBP. Based on our clinical experiences, we also hypothesized that discogenic LBP could be indicated in standing position with flexion and in sitting position. The purpose of the current study was to evaluate the usefulness of our original questions in a medical interview about LBP, which was intended to determine the characteristics of discogenic LBP, and establish a support tool for diagnosing discogenic LBP.

Materials and Methods

Subjects

In the current study, we defined the DDD group as those who suffered from discogenic LBP associated with DDD. The DDD group consisted of consecutive patients from November 2012

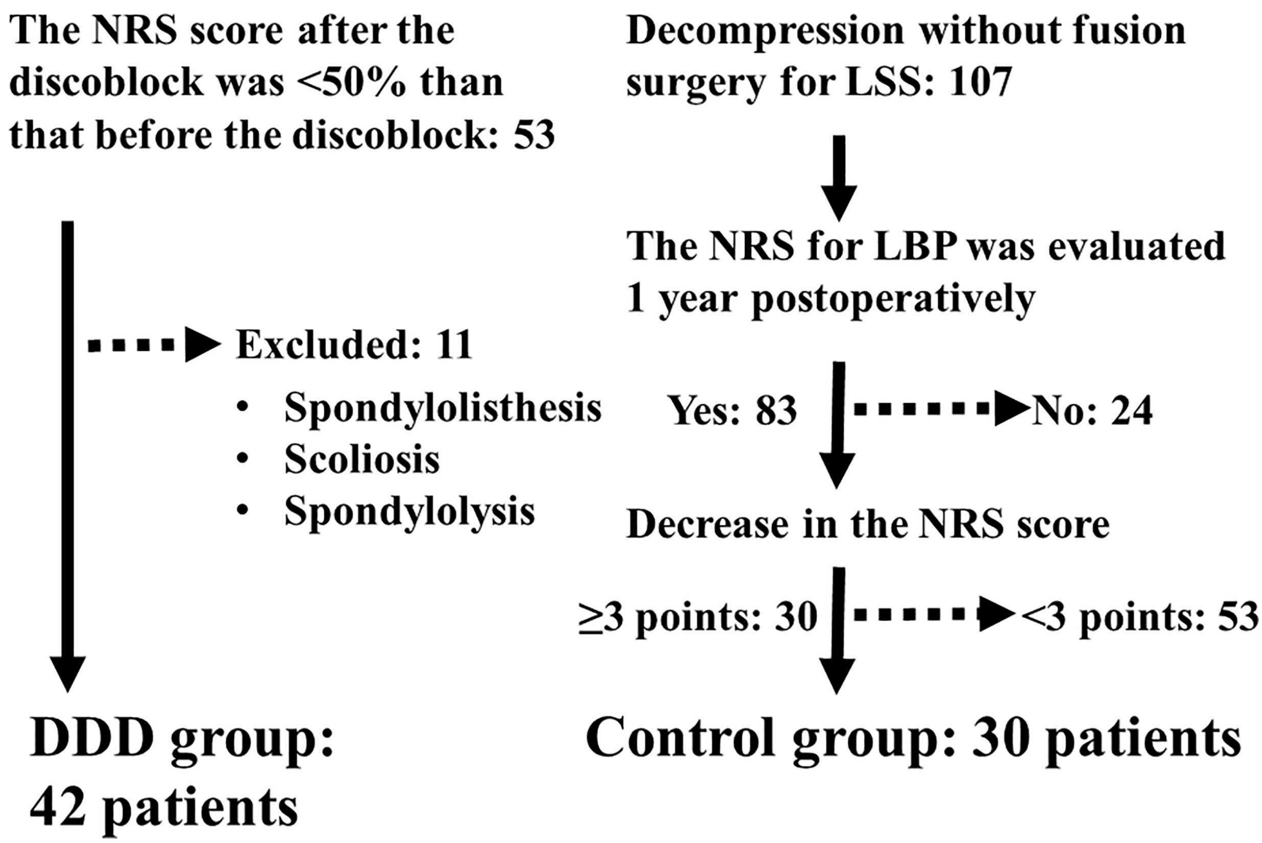

Fig 1. Study flow chart. Forty-two patients were included in the degenerative disc disease (DDD) group, and 30 patients were included in the control group. LBP, low back pain; NRS, numerical rating scale; LSS, lumbar spinal stenosis.

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to April 2014. Fifty-three patients had been diagnosed as having DDD by MRI and discoblock. Of 53 patients, we excluded 11 who had suffered from spondylolisthesis, scoliosis, and spondylolysis accompanied by DDD. Therefore, the DDD group consisted of 42 consecutive patients. We defined the control group as those who had suffered from LBP due to reasons other than DDD. We selected the control group from patients who had been diagnosed as having lumbar spinal stenosis (LSS) and had undergone posterior decompression surgery without fusion. The control group consisted of consecutive patients from April 2012 to December 2013. One hundred and seven patients had undergone decompression surgery for LSS. Of 107 patients, we could evaluate the numerical rating scale (NRS) score of 83 patients' LBP at 1 year postoperatively. Of 83 patients, 30 had a decrease in the postoperative NRS score of greater than or equal to 3 points compared with the preoperative NRS score. We included these 30 patients in the control group. In summary, 72 patients were included in this study, which consisted of 42 in the DDD group and 30 in the control group (Fig 1). We also collected patients' background information, including their age, sex, height, weight, and smoking habit, using a self-written questionnaire. We calculated the body mass index (BMI) from the data of height and weight. We also determined the NRS score of patients' LBP and assessed the Oswestry Disability Index (ODI) score [17] using a self-written questionnaire. We used a validated version of the Japanese ODI, which had been translated from the ODI version 2.0 [18]. The reliability and validity of this version was evaluated in their previous study, and was sufficient to use for outcome studies in Japan. This study was approved by the medical/ethics review board of Iwai Orthopaedic Medical Hospital. Written informed consent was obtained from all the patients.

Definition of discogenic LBP

Although there is no consensus on how to diagnose discogenic LBP, we hypothesized and defined discogenic LBP as LBP that met the following criteria: MRI findings of a degenerated disc, and response to the discoblock into the disc suggestive of LBP. Although a discoblock may be harmful to the disc and it does not necessarily indicate high specificity findings of discogenic LBP, we hypothesized that a positive response to a discoblock indicates discogenic LBP.

At our hospital, well-trained medical clerks ask all patients about their medical history and symptoms during their first visit usually before they see the doctor. For patients who had suffered from lumbar diseases, medical clerks asked them about the following items in a medical interview: whether they had LBP from sitting too long, whether they had LBP while standing after sitting too long, whether they squirmed in a chair after sitting too long, whether they had LBP while washing their face, and whether they had LBP in standing position with flexion via a medical interview. Additionally, we precisely defined and evaluated the region of LBP and depicted it in a diagram for patients (i.e., pain localized between the costal margin and the inferior gluteal folds according to a previous report [19,20]). This was important for standardizing the study protocol for LBP.

We evaluated patients' physical findings, and radiography and MRI findings as needed. If the MRI showed only disc degeneration without disc herniation, spinal stenosis, or any other obvious findings, we suspected DDD. We evaluated disc degeneration on sagittal T2-weighted MRI based on Pfirrmann's grading system [21]. We considered grades $\geq$4 as disc degeneration. When we suspected discogenic LBP associated with DDD and the patient's disability was severe despite conservative therapies, we performed an additional examination (discoblock, a 1-mL injection of 1% lidocaine into the disc suggestive of LBP), and evaluated the degree of LBP both before and after the injection. We hypothesized discogenic LBP associated with DDD when the NRS score for LBP after the discoblock was <50% of that before the discoblock, although it was unclear whether the cutoff reduction rate of 50% was appropriate. When multilevel disc degeneration was shown on MRI, we performed the injections on a different day and evaluated the effectiveness of the injection for each disc.

Statistical methods

We compared the baseline characteristics of both groups, and analyzed the usefulness of the aforementioned five items of the medical interview for diagnosing discogenic LBP. For the age-adjusted analysis, we set the cut-off value at 65 years. Moreover, after identifying significant symptoms of discogenic LBP, we developed a support tool for diagnosing discogenic LBP.

Descriptive statistics were determined and presented as means and standard deviations or frequencies and percentages. Between-group differences in baseline characteristics were evaluated using the chi-square test for categorical variables, and Student's t-test for continuous variables. Age-adjusted odds ratios and 95% confidential intervals for each questionnaire were evaluated by logistic regression analyses. Moreover, we set the scores of each item as integral values from each age-adjusted odds ratio, and performed receiver operating characteristic (ROC) curve analysis to develop a support tool for diagnosing discogenic LBP. Finally, we calculated the area under the ROC curve (AUC), sensitivity, and specificity. An AUC of 1.0 indicated perfect discrimination, and in general, an AUC $\geq$0.7 was considered to indicate acceptable discrimination. Statistical analysis was performed using the JMP 11.0 software program (SAS Institute, Cary, NC, USA). A p value <0.05 was considered significant.

Results

Patients' average age was 53.9 years in the DDD group and 71.1 years in the control group. The ratio of age $\geq$65 years was 16.7% in the DDD group and 30.1% in the control group. There was a significant difference in age between the DDD and control groups ($p < 0.0001$ and $p = 0.0002$, respectively). However, there were no significant differences in the other baseline characteristics such as sex, BMI, smoking habit, NRS score, and ODI score. There were significant differences between the groups for each item of the medical interview about LBP after sitting too long ($p < 0.0001$), LBP while standing after sitting too long ($p < 0.0001$), squirming in a chair after sitting too long ($p = 0.011$), LBP while washing one's face ($p < 0.0001$), and LBP in standing position with flexion ($p < 0.0001$) (Table 1).

In the age-adjusted analyses, the odds ratios of LBP after sitting too long, LBP while standing after sitting too long, squirming in a chair after sitting too long, LBP while washing one's face, and LBP in standing position with flexion were 10.5, 8.5, 4.0, 10.8, and 11.8, respectively. There were significant differences for all five items of the medical interview between the groups (Table 2). The integer scores were 11, 9, 4, 11, and 12, respectively, and the sum of the points of the five scores ranged from 0 to 47. Results of the ROC analysis were as follows: cut-off value, 31 points; AUC, 0.92302; sensitivity, 100%; and specificity, 71.4%.

Discussion

We examined five items of our medical interview regarding discogenic LBP. We hypothesized and defined discogenic LBP as a degenerated disc on MRI and response to a discoblock used for the disc suggestive of LBP.

Table 1. Baseline characteristics of patients in the DDD group and control group.

	DDD group (n = 42)	Control group (n = 30)	*P* value
• Age[1)]	53.4 ± 16.2	71.1 ± 9.4	<0.0001*
• Age ≥65 years[2)]	12 (16.7)	22 (30.1)	0.0002*
• Female sex[2)]	15 (35.7)	7 (23.3)	0.26
• BMI (kg/m^2)[1)]	24.2 ± 3.2	24.9 ± 2.7	0.36
• Smoking habit[2)]	28 (66.7)	16 (53.3)	0.25
• Current smoking habit[2)]	9 (21.4)	6 (20.0)	0.88
• NRS score[1)]	6.2 ± 2.3	6.2 ± 1.7	0.99
• ODI score[1)]	37.2 ± 13.3	37.8 ± 9.9	0.84
• LBP after sitting too long[2)]	35 (83.3)	9 (30.0)	<0.0001*
• LBP while standing after sitting too long[2)]	35 (83.3)	11 (36.7)	<0.0001*
• Squirming in a chair after sitting too long[2)]	33 (78.6)	15 (50.0)	0.011*
• LBP while washing one's face[2)]	31 (73.8)	6 (20.0)	<0.0001*
• LBP in standing position with flexion[2)]	22 (52.4)	2 (6.7)	<0.0001*

Data are shown as mean ± standard deviation or number of participants (%).

*: $P < 0.05$

[1)]: Student's t-test

[2)]: chi-square test.

DDD, degenerative disc disease; ODI, Oswestry Disability Index; NRS, numerical rating scale; LBP, low back pain.

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Table 2. Age-adjusted odds ratio, 95% confidential interval, and p-value for each item of the medical interview regarding LBP.

	Odds ratio	95% confidential interval	*P* value	Integer score
• LBP after sitting too long	10.5	3.3–39.4	<0.0001*	11
• LBP while standing after sitting too long	8.5	2.7–31.9	0.0002*	9
• Squirming in a chair after sitting too long	4.0	1.3–13.7	0.016*	4
• LBP while washing one's face	10.8	3.3–41.3	<0.0001*	11
• LBP in standing position with flexion	11.8	2.8–82.2	0.0004*	12

*: $P < 0.05$.
LBP, low back pain.

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No significant difference was observed in the baseline characteristics between the two groups, except with regard to age. The DDD group consisted of significantly younger patients and thus had a wider generation than the control group, although disc degeneration progresses with advancing age [5]. The reason for this may be caused by our definition of the control group.

We intended to define the control group as those who had LBP that was not mild for reasons other than discogenic LBP. The NRS score of 6.2 and ODI score of 37.8 in the control group indicate that the LBP was not mild, thus it was equivalent to that in the DDD group in terms of severity. However, it is difficult to confirm whether LBP was discogenic. Accordingly, we focused on patients who had been diagnosed as having LSS. Some patients with LSS have LBP, whereas other patients do not have LBP. The MRI scans of patients with LSS often show degenerated discs in addition to spinal stenosis, because disc degeneration progresses with advancing age [5] and LSS is often present in older people. However, the cause of LBP in patients with LSS is not necessarily derived from disc degeneration. It can often improve after decompression surgery without fusion [22], which indicates that compression of the dura itself can present as LBP in these patients. We hypothesized that improvement of LBP in the control group resulted from decompression of the dura itself and that it was not associated with disc degeneration, although the lack of a negative response to the discoblock in the control group was not evaluated in this study. We excluded patients who had undergone decompression combined with fusion surgery because the improvement of LBP by fusion surgery implies the co-existence of discogenic LBP. We defined a clinically meaningful improvement in LBP postoperatively as a reduction in the NRS score of $\geq$3 points, according to a study that reported that the cut-off value for the decrease in the NRS score is 2.5 for successful lumbar surgery [23]. Therefore, we considered the cause of LBP in the control group as LBP caused by LSS itself and that it was not associated with DDD. As LSS is often present in more aged people, there was a significant difference in age between the two groups. Therefore, we performed age-adjusted analyses. We defined the cut-off age as 65 years. Since the prevalence of LBP increases with advancing age [2], we did not underestimate the DDD group, which was younger than the control group.

There were significant differences between the groups in all the five items of our medical interview for analyses adjusted and not adjusted by age. The odds ratios of only the items of LBP after sitting too long, LBP while washing one's face, and LBP in standing position with flexion were $>$10. One reason for this may be because the results seemed to be associated with a higher intradiscal pressure in sitting and standing positions with flexion [24–28]. LBP while standing after sitting too long was significantly associated with discogenic LBP. The motion of standing after sitting too long includes changing the status of both the disc and facet, which is often degenerated in patients with LSS; however, our result indicated that LBP was discogenic. Therefore, the result may have been derived from the increasing intradiscal pressure. The items

LBP while washing one's face and LBP in standing position with flexion may be similar; however, we had intended to differentiate mild flexion of the trunk, such as the posture for washing one's face from full flexion of the trunk. In terms of the results, both items can significantly indicate discogenic LBP. The results may have also been derived from increasing intradiscal pressure.

Another reason why the results seemed to be similar to previous reports may be because being in one position too long advances disc degeneration [29, 30]. We assumed that being in one position too long caused discogenic LBP. LBP after sitting too long was also significantly associated with discogenic LBP. The high odds ratio of 10.5 for sitting too long in the current study may have been derived from being in the same position too long rather than from increasing intradiscal pressure itself. The symptom of squirming in a chair after sitting too long was also significantly associated with discogenic LBP. There has been no report about the relationship between LBP and squirming in a chair after sitting too long. This may have also been derived from being in the same position too long.

The AUC of 0.92302 was considered to indicate acceptable discrimination. ROC analysis indicated the cut-off value of 31 in our scoring system for diagnosing discogenic LBP, which meant that >31 points of the total 47 points are needed to diagnose discogenic LBP. Considering each item of the medical interview, we can diagnose discogenic LBP in all cases if four or five of the five items are positive, and in some cases if three of five items are positive.

There were some limitations to the current study. First, answers to the medical interview were not necessarily accurate. The subjective evaluation of the patients' own LBP can vary, i.e., positive or negative responses can differ depending on the medical interview. However, the results of the current study showed the high odds ratios of the five items, so we considered the results acceptable. Second, we did not evaluate the effectiveness of a discoblock in patients in the control group. The MRI scans of patients with LSS often show degenerated discs in addition to spinal stenosis. We omitted the evaluation of degenerated disc by discoblock in the control group. Patients had been diagnosed as having LSS based on clinical features such as lower limb symptoms and MRI findings; thus, an additional discoblock seemed unnecessary from clinical and ethical standpoints. However, if there were negative findings among the control group, our method for diagnosing discogenic LBP is more reliable. Third, we could not diagnose the degenerated disc responsible for LBP by the medical interview without performing the discoblock if there were multiple degenerated discs on the patient's MRI. Fourth, we did not evaluate any other diseases such as LBP associated with sacroiliac joint dysfunction, LBP of the zygapophyseal joint, and major disturbances of the central nervous system associated with chronic pain. Fifth, there was selection bias among our patients. All patients in the DDD group had undergone surgery, although the therapy for discogenic LBP associated with DDD was usually considered conservative. Although patients in the DDD group who were sent to our hospital had a tendency of having severe LBP, patients from one hospital cannot represent patients with discogenic LBP in general.

Conclusions

In accordance with our hypotheses that discogenic LBP exists and that a positive response to a discoblock indicates discogenic LBP, all five items of our medical interview about LBP (i.e., LBP after sitting too long, LBP while standing after sitting too long, squirming in a chair after sitting too long, LBP while washing one's face, and LBP in standing position with flexion) were useful for diagnosing discogenic LBP associated with DDD. We can diagnose discogenic LBP in all cases if four or five of the five items of the medical interview are positive, and in some cases, if three of five items are positive.

Supporting Information

S1 File. Supporting information. Dataset of this study.
(XLS)

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Investigation: JT HI.

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Supervision: KM ST.

Writing – original draft: JT.

Writing – review & editing: JT HO JK.

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RESEARCH ARTICLE Open Access

The impact of depression among chronic low back pain patients in Japan

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Abstract

Background: Chronic low back pain (CLBP) is associated with significant disability and reductions in health related quality of life (HRQoL), which can negatively impact overall function and productivity. Depression is also associated with painful physical symptoms, and is often present in patients with chronic pain. However, the incremental burden associated with depression or symptoms of depression among CLBP patients is not well understood. The objective of this study was to investigate the impact of depression on HRQoL in CLBP and to assess the relationship between depression and work impairment and healthcare use among CLBP patients in Japan.

Methods: Data were extracted from the 2014 Japan National Health and Wellness Survey ($N = 30,000$). CLBP was defined by report of diagnosed low back pain ≥3 months duration. Depression was assessed using the Patient Health Questionnaire (PHQ-9). Measurements assessed included pain, HRQoL, labor force participation, work productivity and healthcare utilization. Patients with depression (PHQ-9 ≥ 10) were compared to patients without depression (PHQ-9 < 10) using t-tests for continuous and count variables and chi-square for categorical variables, which were followed by generalized linear models adjusted for covariates. The association between presenteeism and other patient outcomes and characteristics was analysed using nonparametric correlations (Spearman's rho).

Results: Depressed CLBP patients had significantly more severe pain and higher levels of pain compared with patients without depression ($P < 0.001$). Depression was associated with worse HRQoL in CLBP patients. Presenteeism, overall work impairment and activity impairment were 1.8, 1.9 and 1.7 times as high, respectively, among those with depression relative to those without depression. CLBP patients with depression had almost twice as many healthcare provider visits in 6 months than those without depression. The pattern of results remained consistent after adjustment for sociodemographic and general health characteristics. Analysis also indicated presenteeism was closely related to overall work impairment (rho = 0.99).

Conclusions: Depression among CLBP patients in Japan was associated with higher pain scores and lower HRQoL scores, as well as lower labor productivity and increased healthcare use. Screening for depression in CLBP patients should be an essential part of CLBP patient care.

Keywords: Low back pain, Chronic low back pain, Depression, Quality of life

Background

Low back pain (LBP) is a common health issue affecting at least 80 % of individuals during their lifetime [1] and poses a severe economic burden on individuals and their communities [2–5]. The Global Burden of Disease Study 2013 found that globally, back pain was one of the leading cause of years lived with disability (YLDs) [6]. In Japan, back pain is the top cause of YLD and the 2nd and 4th most frequent reason for outpatient visits for women and men, respectively [6, 7].

One of the main characteristics of LBP is recurrence, and a number of patients develop chronic LBP (CLBP). In Japan CLBP is the most prevalent type of chronic pain [8], with a prevalence estimated at 23 %, and 11–12 % of the population is disabled by it [9]. Though considerable research has been directed at understanding back pain, most Japanese epidemiological studies examine LBP in general, with few focused on CLBP [10–12].

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While burdensome in its own right, pain is also risk factor for depression, and many studies have examined the co-occurrence of pain and depression [13–16]. The comorbidity is clinically well established but the underlying mechanisms are not well understood, though a potential explanation is disruption of the mesolimbic dopamine system [17, 18]. Recent data from animal models indicate that regulation of dopamine activity in the ventral tegmental area (VTA) mediates depressive and anxiogenic responses [19] suggesting a neurological link between depression and chronic pain.

CLBP in particular is often co-morbid with depression [20], a main cause of disability worldwide [6]. Depression increases the risk of developing LBP [21], and CLBP is affected by the patient's mental state [22]. In spite of that, the mental state of most CLBP patients is not routinely assessed. Thus, in chronic pain, psychosocial risk factors become relevant, and are important to explain how individuals respond to back pain. Recent studies have demonstrated that psychosocial factors are important risk factors for LBP among Japanese workers [22, 23]; however, data examining the role of depression in CLBP patients in Japan is lacking.

The objective of this study was to investigate the impact of depression on health-related quality of life (HRQoL) in CLBP, as well as to assess the relationship between depression and work impairment and healthcare use among CLBP patients in Japan.

Methods

Sample

Data were extracted from the 2014 Japan National Health and Wellness Survey (NHWS) (Kantar Health, New York, USA), which is a general health survey designed to reflect the health of the population in Japan ($N = 30{,}000$). The survey is administered via the Internet, with potential respondents identified through opt-in survey panels. Participants were stratified by gender and age groups to ensure representative samples, with quotas set through the distribution of age and gender within the Japanese population aged ≥18 years.

Respondents were considered to have CLBP if they had been diagnosed with back pain by a doctor, reported experiencing back pain in the past month, and experienced back pain ≥ 3 months. Three months duration of LBP is considered chronic according to both Japanese and US treatment guidelines [24, 25]. Depression symptoms and severity of depression over the last two weeks was assessed using the Patient Health Questionnaire (PHQ-9), a validated scale used to screen for depression and assess its severity [26]. The scale evaluates depression by measuring the frequency of anhedonia, depressed mood, sleep disturbance, lack of energy, appetite disturbance, negative self-feelings, difficulty concentrating, psychomotor retardation or agitation, and thoughts of self-harm. A single-item measure of the interference of these symptoms was also included. Respondents who scored ≥ 10 (the cutoff associated with moderate depression) were considered to have depression regardless of whether they indicated a diagnosis of depression, and respondents scoring <10 (associated with minimal or mild depression) were considered not to have depression; this value has shown good sensitivity and specificity for major depression in previous research [27].

Measures

Using a 0–10 numeric rating scale (NRS) anchored by *No Pain* (0) and *Pain as Bad as You Can Imagine* (10), respondents rated the severity of their LBP, as well as the severity of their pain overall, as mild (0–3), moderate (4–6), or severe (7–10). The NRS was completed for both current and pain in the past week. Respondents indicated how frequently they experienced problems with pain on a 6-point scale ranging from *Daily* to *Once a month or less often*. HRQoL was measured using the revised Medical Outcomes Study 36-Item Short Form Survey Instrument (SF-36v2;[28]). This is a multipurpose, generic HRQoL instrument comprising 36 questions. The instrument is designed to report on eight health concepts (physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH)). The versions of the scores used in this study were based on the Japanese norms, which have a mean of 50 and standard deviation of 10 in the Japanese population [29]. Scores can be interpreted relative to this population average of 50 as well as with other comparison groups of interest. Higher scores indicate better quality of life.

Mental component summary (MCS), physical component summary (PCS), and short form 6D (SF-6D) health utility scores were also calculated according to the standard scoring algorithms. These scores are based on the US (MCS & PCS) and UK (SF-6D) general populations, but are commonly reported in studies outside those countries as the scores allow for comparison across international populations.

Labor force participation was defined as being employed or unemployed but looking for work. Work productivity was assessed using the Work Productivity and Activity Impairment (WPAI) questionnaire, a 6-item validated instrument which consists of four metrics: absenteeism (the percentage of work time missed because of one's health in the past seven days), presenteeism (the percentage of impairment experienced while at work in the past seven days because of one's health), overall work productivity loss (an overall impairment estimate that is a combination of absenteeism and presenteeism), and activity impairment (the percentage of impairment in daily activities because of one's health in the past seven days) [30]. Only respondents who reported being employed full-time or part-time provided data for absenteeism, presenteeism, and overall work impairment. All respondents provided data for activity impairment.

Healthcare utilization was defined by the number of healthcare provider visits, the number of hospital emergency room (ER) visits, and the number of times hospitalized in the past six months. The reason for each visit was not included in the questionnaire.

Analysis

The analysis was primarily concerned with the association between the presence of depression, so patients with depression (PHQ-9 ≥ 10) were compared with those without depression (PHQ-9 < 10) using t-tests for continuous and count variables and chi-square for categorical variables. To ensure differences due to confounding variables were not attributed to depression, these tests were followed by regression modelling using generalized linear models adjusting for age, sex, length of LBP diagnosis, Charlson Comorbidity Index (CCI), household income, marital status, university education, body mass index (BMI), cigarette smoking, alcohol use, and exercise to account for sociodemographic characteristics and general health characteristics.

These comparisons according to were supplemented by correlational analysis, using the PHQ-9 score as a continuous measure. Because some outcomes were positively skewed rather than normally distributed, the association between presenteeism and other patient outcomes and characteristics was analysed using nonparametric correlations (Spearman's rho).

Results

Of the participants surveyed, 425 were identified as having CLBP. The average age of a respondent with CLBP was 54 years old, and 44 % were female (Table 1). When assessed according to depression status, CLBP patients with depression (PHQ-9 ≥ 10; $N = 70$) were younger than CLBP patients without depression (PHQ-9 < 10; $N = 355$) by approximately 9 years on average, but did not differ in terms of average CCI score, gender, or employment status. Patients with depression were less likely to be married or live with a partner (Table 1). Patients indicated their LBP was either mild (47 %) or moderate (44 %) rather than severe (9 %). Both overall severity of pain and current level of pain were near the midpoint of the NRS, and almost half reported daily problems with pain. Depression was significantly associated with more severe pain and higher levels of pain, current and in the prior week (Table 1).

CLBP patients with depression had worse HRQoL than CLBP patients without depression (Table 2). Depression was also associated with more impairment while at work (presenteeism). Overall work impairment, which is largely driven by presenteeism, was also significantly higher among CLBP patients with depression. There was no significant difference in absenteeism or rate of labor force participation between CLBP patients with and without depression. Depressed CLBP patients reported more activity impairment than those without depression. Depression was also associated with approximately two more healthcare provider visits among CLBP patients in the 6 month recall period (Table 2).

The pattern of results was consistent after covariates were incorporated into the regression analysis. Adjusted HRQoL scores were lower on all of the eight Japanese norm-based scores. Adjusted mean MCS and PCS using international norms were also lower (Fig. 1).

Regression-adjusted presenteeism and overall work impairment were 1.8 and 1.9 times as high, respectively, among those with depression relative to those without depression (Fig. 2). Activity impairment was 1.7 times as high in patients with depression compared with patients without depression after adjustment for covariates. HCP visits were almost twice as frequent in patients with depression compared with patients without depression. Likewise, work impairment was greater in patients with depression compared with patients without depression.

Analysis of depression based on PHQ-9 scores as a continuous variable also demonstrated the association between depression and pain among CLBP patients. Greater depression was significantly associated with more frequent problems with pain, greater current and past-week severity of pain (based on NRS scores), pain at more sites in addition to LBP, and more presenteeism and overall work impairment ($P < 0.001$, Table 3). Moreover, additional regression analysis conducted using PHQ-9 scores as a continuous variable corroborated the findings, indicating lower HRQoL scores with higher PHQ-9 scores, with the exception of the Japanese PCS score. Pain was likewise worse with greater depression as was presenteeism, overall work impairment, and activity impairment. Consistent with the results shown in Fig. 2, HCP visits were more frequent with greater depression scores, but there was no significant association with ER visits or hospitalizations (data not shown).

When assessing the relationship between work impairment and other characteristic and outcomes, presenteeism was very closely related to overall work impairment (rho = 0.99). Greater presenteeism was associated with more-severe LBP, more-severe pain in the prior week and currently based on the NRS. Although, there was a trend for greater presenteeism being associated with more frequent problems with pain,

Table 1 Characteristics of CLBP patients according to presence of depression

	Total (*N* = 425)	Depression (PHQ-9 ≥ 10) (*N* = 70)	No Depression (PHQ-9 < 10) (*N* = 355)	*P value*
Age, Mean ± SD	53.90 ± 14.16	45.91 ± 13.73	55.48 ± 13.73	<0.001
Female, n (%)	187 (44.00)	33 (47.14)	154 (43.38)	0.562
Employment status, n (%)				0.589
Not currently employed	164 (38.59)	25 (35.71)	139 (39.15)	
Employed	261 (61.41)	45 (64.29)	216 (60.85)	
Annual household income, n (%)				0.079
< ¥3million	83 (19.53)	22 (31.43)	61 (17.18)	
¥3million to < ¥5million	100 (23.53)	15 (21.43)	85 (23.94)	
¥5million to < ¥8million	113 (26.59)	15 (21.43)	98 (27.61)	
¥8million or more	97 (22.82)	12 (17.14)	85 (23.94)	
Decline to answer	32 (7.53)	6 (8.57)	26 (7.32)	
Marital status, n (%)				0.021
Single/Divorced/Separated/Widowed	138 (32.47)	31 (44.29)	107 (30.14)	
Married/living with partner	287 (67.53)	39 (55.71)	248 (69.86)	
Education level, n (%)				0.063
Less than university education	218 (51.29)	43 (61.43)	175 (49.30)	
University education or higher	207 (48.71)	27 (38.57)	180 (50.70)	
Body mass index category, n (%)				0.137
Underweight	52 (12.24)	9 (12.86)	43 (12.11)	
Normal weight	280 (65.88)	39 (55.71)	241 (67.89)	
Overweight	70 (16.47)	16 (22.86)	54 (15.21)	
Obese	19 (4.47 %)	4 (5.71)	15 (4.23)	
Decline to provide weight	4 (0.94 %)	2 (2.86)	2 (0.56)	
Smoking behavior, n (%)				0.088
Never smoked	182 (42.82)	34 (48.57)	148 (41.69)	
Former smoker	132 (31.06)	14 (20.00)	118 (33.24)	
Current smoker	111 (26.12)	22 (31.43)	89 (25.07)	
Alcohol use, n (%)				0.975
Do not drink	116 (27.29)	19 (27.14)	97 (27.32)	
Drink alcohol	309 (72.71)	51 (72.86)	258 (72.68)	
Vigorous exercise at least one day in the past month, n (%)				0.198
Do not exercise	213 (50.12)	40 (57.14)	173 (48.73)	
Exercise	212 (49.88)	30 (42.86)	182 (51.27)	
Charlson comorbidity index, Mean ± SD	0.51 ± 2.23	0.83 ± 3.64	0.44 ± 1.83	0.186
Sleep difficulties, n (%)	82 (19.29)	35 (50.00)	47 (13.24)	<0.001
Severity of LBP, n (%)				<0.001
Mild	186 (47.45)	19 (29.23)	167 (51.07)	
Moderate	172 (43.88)	34 (52.31)	138 (42.20)	
Severe	34 (8.67)	12 (18.46)	22 (6.73)	
Missing	33	5	28	
Severity of pain in the prior week (0–10), Mean ± SD	4.48 ± 2.31	5.80 ± 2.26	4.23 ± 2.23	<0.001
Current severity of pain (0–10), Mean ± SD	4.59 ± 2.28	5.86 ± 2.27	4.34 ± 2.20	<0.001

Table 1 Characteristics of CLBP patients according to presence of depression *(Continued)*

Frequency of problems with pain, n (%)				0.002
Daily	188 (44.24)	44 (62.86)	144 (40.56)	
4–6 times a week	63 (14.82)	12 (17.14)	51 (14.37)	
2–3 times a week	82 (19.29)	10 (14.29)	72 (20.28)	
Once a week	39 (9.18)	3 (4.29)	36 (10.14)	
2–3 times a month	35 (8.24)	0 (0.00)	35 (9.86)	
Once a month or less often	18 (4.24)	1 (1.43)	17 (4.79)	
Type of diagnosing doctor for LBP, n (%)				0.028
General internist	18 (4.24)	4 (5.71)	14 (3.94)	
Gynecologist	5 (1.18)	0 (0.00)	5 (1.41)	
Orthopedist	353 (83.06)	54 (77.14)	299 (84.23)	
Rheumatologist	4 (0.94)	3 (4.29)	1 (0.28)	
Pain management specialist	3 (0.71)	1 (1.43)	2 (0.56)	
Other	42 (9.88)	8 (11.43)	34 (9.58)	
Type of prescribing doctor, n (%)				0.150
General internist	28 (16.87)	6 (15.38)	22 (17.32)	
Gynecologist	2 (1.20)	0 (0.00)	2 (1.57)	
Orthopedist	116 (69.88)	24 (61.54)	92 (72.44)	
Rheumatologist	5 (3.01)	3 (7.69)	2 (1.57)	
Pain management specialist	1 (0.60)	0 (0.00)	1 (0.79)	
Other	14 (8.43)	6 (15.38)	8 (6.30)	
Missing	259	31	228	
Duration of LBP (months), Mean ± SD	112 ± 120	96 ± 99	115 ± 123	0.227
Current use of a prescription medication for pain, n (%)				0.002
No	259 (60.94)	31 (44.29)	228 (64.23)	
Yes	166 (39.06)	39 (55.71)	127 (35.77)	
Current use of NSAIDs prescription for pain, n (%)				0.049
No	40 (24.10)	14 (35.90)	26 (20.47)	
Yes	126 (75.90)	25 (64.10)	101 (79.53)	
Missing	259	31	228	
Use of an OTC product for pain, n (%)				0.861
No	306 (72.00)	51 (72.86)	255 (71.83)	
Yes	119 (28.00)	19 (27.14)	100 (28.17)	
Use of an herbal product for pain, n (%)				0.441
No	413 (97.18)	69 (98.57)	344 (96.90)	
Yes	12 (2.82)	1 (1.43)	11 (3.10)	

[a]NSAIDS are prescription drugs in Japan. *CLBP* chronic low back pain, *LBP* low back pain, *NSAIDs* non-steroidal anti-inflammatory drugs, *OTC* over-the-counter, *PHQ-9* Patient Health Questionaire-9

it did not reach statistical significance ($P = 0.08$). Presenteeism was moderately related to the severity of depression according to the PHQ-9 score (Table 4).

Discussion

Our results demonstrated that CLBP patients with depression had significantly more severe and higher levels of pain, as well as significantly worse HRQoL compared with CLBP patients without depression. These observations are consistent with those recently published by Hiyama et al., which showed that depressed patients and those with neuropathic LBP had a higher level of pain and poorer quality of life compared with non-depressed patients [16]. The majority of patients had mild (47 %) or moderate (44 %) LBP. Current and prior week pain severity scores were similar (4.6/10 vs 4.5/10)

Table 2 Outcomes among CLBP patients according to presence of depression

	Total (N = 425)	Depression (PHQ-9 ≥ 10) (N = 70)	No Depression (PHQ-9 < 10) (N = 355)	
	Mean ± SD	Mean ± SD	Mean ± SD	*P* value
Health status: Japanese norm-based scores				
Physical functioning	44.36 ± 15.43	37.73 ± 17.9	45.66 ± 14.57	<0.001
Role physical	42.26 ± 14.29	32.51 ± 16.28	44.19 ± 13.05	<0.001
Bodily pain	39.59 ± 8.89	34.61 ± 9.56	40.57 ± 8.43	<0.001
General health	42.59 ± 10.96	33.25 ± 9.24	44.43 ± 10.32	<0.001
Vitality	42.87 ± 10.92	30.98 ± 9.26	45.22 ± 9.63	<0.001
Social functioning	43.03 ± 13.36	30.51 ± 13.63	45.49 ± 11.85	<0.001
Role emotional	44.7 ± 13.14	32.34 ± 15.13	47.14 ± 11.22	<0.001
Mental health	45.17 ± 11.2	32 ± 9.54	47.77 ± 9.55	<0.001
Health status: International scores				
Mental component	45.01 ± 10.92	31.27 ± 10.04	47.72 ± 8.85	<0.001
Physical component	46.81 ± 7.65	44.08 ± 7.96	47.35 ± 7.48	0.001
Health utility (SF-6D)	0.67 ± 0.12	0.56 ± 0.09	0.69 ± 0.11	<0.001
Work impairment				
Absenteeism %	4.92 ± 17.87	7.33 ± 22.37	4.39 ± 16.75	0.335
Presenteeism %	31.59 ± 28.08	46.43 ± 26.12	28.43 ± 27.52	<0.001
Overall work impairment %	33.90 ± 30.08	49.81 ± 27.74	30.40 ± 29.50	<0.001
Activity impairment %	37.34 ± 29.90	56.00 ± 27.21	33.66 ± 29.05	<0.001
HCP visits (past 6 months)	12.64 ± 16.24	19.67 ± 21.07	11.25 ± 14.75	<0.001

HCP healthcare provider

and almost half of all patients reported daily pain problems. Overall sociodemographic patient characteristics were similar between the two groups of CLBP patients with the exception of age, marital status and sleeping difficulties. CLBP patients with depression were significantly younger, on average 9 years, compared with CLBP patients without depression. These observations tend to be consistent with observations for major depressive disorder where estimates in the general population are 15–17 %, while the 1-year prevalence rate in individuals ≥ 65 years is lower, at 1–4 % [31]. Significantly more CLBP patients with depression were single/divorced compared with CLBP patients without depression (44.3 % vs 30.1 %). However, differences in marital status and sleeping difficulties were consistent with differences observed in major depression disorder [27].

Epidemiological, cross-sectional, and prospective studies suggest that insomnia, chronic pain and depression are a cluster of symptoms that are mutually interactive. Studies using a variety of methods, including neuroimaging,

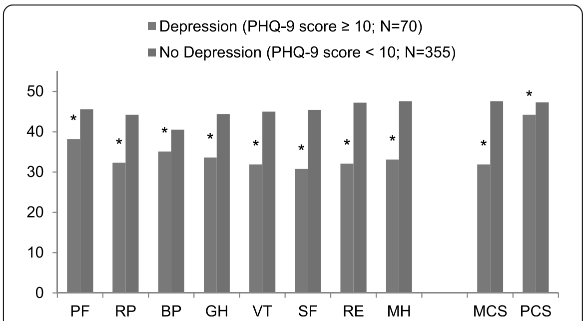

Fig. 1 Adjusted mean HRQoL scores among CLBP patients according to presence of depression. *$p < 0.05$

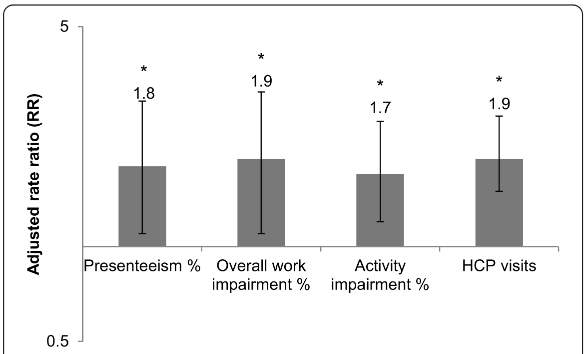

Fig. 2 Adjusted impairments and healthcare visit rates among depressed CLBP patients relative to those without depression. *$p < 0.05$. Results are presented on a logarithmic scale; values above 1 (x-axis) indicate increased impairment and resource use among CLBP patients with depression

Table 3 Correlations between depression, pain, and work impairment among CLBP patients

	Spearman's rho with PHQ-9 score[a]	*P* value
Frequency of problems with pain	0.236	<0.001
Current severity of pain (based on NRS score)	0.289	<0.001
Severity of pain in the prior week (based on NRS score)	0.332	<0.001
Additional pain sites (number, 0–6)	0.387	<0.001
Presenteeism %	0.340	<0.001
Overall work impairment %	0.342	<0.001

[a]Correlation is significant at the 0.01 level (2-tailed)
CLBP chronic low back pain, *NRS* numeric rating scale, *PHQ-9* Patient Health Questionnaire

suggest the mesolimbic dopamine system has been proposed as a key factor in promoting the comorbidity of this cluster of symptoms, [32] and our observations of both higher ratings of pain severity as well as greater prevalence of sleep difficulties among CLBP patients with depression are additional supportive evidence to this body of data.

The adjusted mean HRQoL scores in the CLBP depression group were lower than in the CLBP group without depression. The health status using both Japanese norm-based as well was international scores, indicated significantly poorer outcomes for CLBP patients with depression compared with CLBP patients without depression. Lower PCS scores in CLBP patients with depression are indicative that a decline of mental health could have an effect on physical health in CLBP patients. A similar relationship has been reported among CLBP patients in the United Kingdom, in whom depression as measured by the Hospital Anxiety and Depression Scale (HADS) was correlated with PCS scores [33]. Labor force and absenteeism did not differ by depression status, potentially because of Japanese working habits, where there is a tendency for less sick leave claims compared to other countries [34]. However, presenteeism, overall work and activity impairment were lower in CLBP patients with depression, demonstrating that, even though employees are present at work, they are less productive than those CLBP patients without depression. Additional analyses indicated that presenteeism was closely related to overall work impairment. The current study also demonstrates more frequent use of healthcare among CLBP patients who have depression, consistent with the relationship between depression and healthcare visits recently demonstrated in the US using National Health and Nutrition Examination Survey data [35].

Table 4 Correlations between presenteeism, pain, and depression among employed CLBP patients

	Spearman's rho with presenteeism	*P* value
Overall work impairment %	0.990[a]	<0.001
Severity of lower back pain	0.267[a]	<0.001
Severity of pain in the prior week (based on NRS)	0.297[a]	<0.001
Current severity of pain (based on NRS)	0.245[a]	<0.001
Frequency of problems with pain	0.115	0.077
Sites of pain in addition to LBP (number, 0–6)	0.239[a]	0.002
Depression severity based on PHQ-9	0.342[a]	<0.001

[a]Correlation is significant at the 0.01 level (2-tailed)

Treatment approaches, especially for Japanese workers, have focused on ergonomic approaches in the management of LBP. Consistent with a focus on musculoskeletal symptoms the majority of patients surveyed in our study were diagnosed with LBP by an orthopedist. However, recent studies highlight the importance of psychosocial risk factors in the development of CLBP [22, 23] and our data further highlights the need for mental health evaluation and treatment in addition to physical assessment and therapy.

One limitation of our study is that the analysis was cross-sectional. Therefore our results cannot indicate whether increased pain leads to depression, or whether depression leads to increased pain. Another limitation is selection bias that may not result in an all-encompassing representation of all patients with CLBP. The data were derived from opt-in surveys completed over the Internet. Compared to the general population our study population could be over-representative of individuals who live in urban environments and are technology literate.

Nakamura et al. has shown that chronic musculoskeletal pain does not necessarily improve with treatment and that patients have a high degree of dissatisfaction with it [11, 12]. Ineffective treatment may lead to "doctor shopping". In our study, a significantly higher number of CLBP patients with depression than those without depression were using prescription pain medication (55.7 % vs 35.8 %, $P = 0.002$) indicating that depressed CLBP patients not only suffer more but may also find treatment less effective. Moreover, increased mental and physical suffering often require assistance. All these factors pose undue strain and increase societal cost.

Conclusion

We have demonstrated that depression among CLBP patients is associated with higher pain scores and lower HRQoL scores, as well as lower labor productivity and increased healthcare use. Our results underscore the need to screen for depression in CLBP patients as an essential part of CLBP patient care.

Abbreviations

BMI: Body mass index; BP: Bodily pain; CCI: Charlson Comorbidity Index; CLBP: Chronic low back pain; ER: Emergency room; GH: General health;

HCP: Healthcare provider; HRQoL: Health-related quality of life; LBP: Low back pain; MCS: Mental component summary; MH: Mental health; NHWS: National Health and Wellness Survey; NRS: Numeric rating scale; NSAIDs: Non-steroidal anti-inflammatory drugs; OTC: Over-the-counter; PCS: Physical component summary; PF: Physical functioning; PHQ-9: Patient Health Questionnaire; RE: Role emotional; RP: Role physical; SF: Social functioning; SF-36v2: Medical Outcomes Study 36-Item Short Form Survey Instrument; SF-6D: Short form 6D; VT: Vitality; VTA: Ventral tegmental area; WPAI: Work Productivity and Activity Impairment; YLD: Years lived with disability

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Availability of data and materials
The dataset supporting the conclusions of this article is proprietary to Kantar Health and will not be shared.

Authors' contributions
TT conceived the study idea. JV conducted the statistical analysis. TT, KM, HS, and JV participated in the interpretation of the results and revision of the manuscript for important intellectual content, and have read and approved the final version of the manuscript.

Competing interests
TT is a full-time employee and minor stock holder of Shionogi & Co., Ltd., & HS is a full-time employee of Shionogi & Co. Ltd. KM has received speaking fees from Shionogi & Co., Ltd., Ayumi Pharmaceutical Co., Eli Lilly Japan K.K., Ono Pharmaceutical Co., Ltd., Pfizer Japan Inc., Nippon Zoki Pharmaceutical Co., Ltd., Eisai Co., Ltd., and Teijin Pharma Ltd.; has received research grants from Pfizer Japan Inc., Eisai Co., Ltd., Ayumi Pharmaceutical Co., Nippon Zoki Pharmaceutical Co., Ltd., Ono Pharmaceutical Co., Ltd., Lilly Japan K.K., Sumitomo Dainippon Pharma Co., Ltd., Astellas Pharma Inc., TOTO Ltd., and Okamura Co.; and is a consultant to Shionogi & Co., Ltd. JV is an employee of Kantar Health, which received fees from Shionogi & Co. Ltd., for access to survey data, analysis, and reporting.

Consent for publication
Not applicable.

Ethics approval and consent to participate
The 2014 Japan NHWS was reviewed for exemption determination by Pearl IRB (Indianapolis, IN, USA; study number 14-KAN-106) prior to participant recruitment and found to meet the exemption requirements under 45CFR46.101(b)[2]. All respondents viewed an on-line informed consent form and indicated their consent to participate prior to responding to the survey. No ethical review was undertaken specific to the analysis of anonymous data presented in this report.

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CASE REPORT

Potential use of ^{18}F-FDG-PET/CT to visualize hypermetabolism associated with muscle pain in patients with adult spinal deformity: a case report

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Abstract Patients with adult spinal deformity (ASD) are surgically treated for pain relief; however, visualization of the exact origin of the pain with imaging modalities is still challenging. We report the first case of a 60-year-old female patient who presented with painful degenerative kyphoscoliosis and was evaluated with flourine-18-fluoro-2-deoxy-D-glucose positron emission tomography/computed tomography (^{18}F-FDG-PET/CT) preoperatively. Because her low back pain was resistant to conservative treatment, she was treated with posterior spinal correction and fusion surgery from Th2 to the ilium. One year after the surgery, her low back pain had disappeared completely. In accordance with her clinical course, ^{18}F-FDG-PET imaging revealed the uptake of ^{18}F-FDG in the paravertebral muscles preoperatively and showed the complete absence of uptake at 1 year after surgery. The uptake site coincided with the convex part of each curve of the lumbar spine and was thought to be the result of the increased activity of paravertebral muscles due to their chronic stretched state in the kyphotic posture. This case report suggests the possibility of using ^{18}F-FDG-PET/CT to visualize increased activity in paravertebral muscles and the ensuing pain in ASD patients.

Keywords Adult spinal deformity · 18 F-FDG-PET/CT · Low back pain · Muscle pain · Kyphosis · Scoliosis

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Introduction

Adult spinal deformity (ASD) affects a large number of the elderly, and its prevalence is increasing [1–3]. ASD patients have greater functional limitations and worse quality of life than the normal population [4–8]. In particular, sagittal imbalance is correlated with pain; however, the precise etiology of this condition remains unknown [9]. The relationship between sagittal imbalance and low back pain (LBP) was first reported by Takemitsu et al., who defined a new condition called lumbar degenerative kyphosis [10]. In their study, the authors provided evidence that the paravertebral muscles in patients with lumbar degenerative kyphosis are weak and atrophic, with fatty infiltration, and speculated that LBP in these patients is probably caused by fatigue in these weak extensor muscles [10]. To date, some studies have reported increased activity in the paravertebral muscles in the kyphotic position; however, visualization of this increased activity or the ensuing pain in the muscles is still challenging [11, 12]. Here, we report the first case of a patient who presented with painful degenerative kyphoscoliosis and was evaluated with flourine-18-fluoro-2-deoxy-D-glucose positron-emission tomography/computed tomography (^{18}F-FDG-PET/CT) preoperatively. In this case, the uptake of ^{18}F-FDG in the paravertebral muscles was detected preoperatively, and the increased accumulation was confirmed to disappear at 1 year after surgery, along with the disappearance of her pain.

This case report suggests for the first time the possibility of using ^{18}F-FDG-PET/CT to visualize the hypermetabolic painful paravertebral muscles in ASD patients. Because visualization of the exact origin of the pain in ASD patients has not been achieved by other imaging modalities to date, this case report may assist in opening a new frontier in the management of ASD patients.

Case report

A 60-year-old female patient presented with severe LBP. The radiographic examination of her spine showed degenerative kyphoscoliosis with rotation of the lumbar vertebrae (Fig. 1a, b). Although she was receiving treatment for rheumatoid arthritis (RA), her RA was well controlled and physical examination revealed that her LBP was caused by a spinal deformity. She had no diabetes mellitus. As her pain was resistant to conservative treatment, surgery was planned.

Incidentally, ^{18}F-FDG-PET/CT was performed immediately prior to the operation at the Department of Endocrine Surgery of our hospital for the follow-up of thyroid carcinoma that had been resected 1 year before her first visit to our department. The ^{18}F-FDG-PET/CT was acquired as follows: the patient fasted at least 5 h, and then FDG (296 MBq) was injected with the patient at rest in the supine position. Her plasma glucose level was 93 mg/dl. The PET scan was started 50 min after the injection with the PET-CT scanner (Aquiduo, Toshiba Medical Systems, Otawara, Japan). ^{18}F-FDG-PET/CT images revealed the uptake of ^{18}F-FDG in the bilateral paravertebral muscles of the lumbar spine (Fig. 1c-f). Notably, each uptake site was asymmetrical and coincided with the convex part of the respective curve of the lumbar spine (Fig. 1c–f). The maximum standardized uptake value (SUV-max) was 9.7 on the right side and 4.9 on the left side.

At first, soft tissue metastasis was suspected based on these results. However, magnetic resonance imaging (MRI) showed no evidence of soft tissue tumor (Fig. 1g, h); thus, the uptake was considered to be the result of increased activity in the paravertebral muscles due to the chronic stretching of the muscles in the kyphoscoliotic posture.

As the LBP was not improved by conservative treatment, we performed surgery. At first, the patient was treated with posterior spinal fusion from Th10 to the ilium with interbody fusion and decompression at the level of L3/4, L4/5, and L5/S. Although a spinal orthosis was applied postoperatively, proximal junctional failure with compression fracture of Th11, which caused severe paraplegia, occurred at 2 months after the primary operation. Therefore, we performed revision surgery, extending the fusion level to Th2 (Fig. 2a, b).

After the revision surgery, the postoperative course was uneventful, and the paraplegia gradually improved. One year after the revision surgery, the patient recovered her ability to walk alone with a single T-cane, and her LBP disappeared completely. The patient-oriented questionnaires that were completed preoperatively and at 1 year after the revision surgery revealed improvement of the patient's pain and quality of life. Besides the scores in the numeric rating scale for LBP, the disease-specific outcomes, including the results of the Roland-Morris Disability Questionnaire and Oswestry Disability Index test, improved remarkably (Table 1) [13–16]. To avoid the presence of overcorrection artifacts due to metallic implants on ^{18}F-FDG-PET/CT, conventional ^{18}F-FDG-PET was performed at 1 year after the revision surgery as follow-up of the patient's thyroid carcinoma. This imaging examination showed the complete disappearance of the increased uptake in the paravertebral muscles (Fig. 2c, d).

Discussion

With the development of surgical techniques and the improvement in implants, many ASD patients are treated surgically at present; however, the revision rates can reach 9 % in the long-term follow-up. Therefore, avoiding revision surgery is one of the aims in the care of ASD patients [17]. The main reasons for requiring surgery in ASD patients are persistent severe LBP, gastroesophageal reflux disease, and trunk imbalance, among which LBP is the most frequent reason. From this point of view, the preoperative accurate diagnosis of the origin of the pain is crucial to avoid multiple operations. Thus, visualization of pain in ASD patients is one of the ultimate goals; however, such a diagnostic imaging system had not been established to date.

^{18}F-FDG-PET/CT is a well-established hybrid imaging modality used in oncology, cardiology, and neurology; however, its application in the evaluation of skeletal muscles is still under investigation. ^{18}F-FDG is a glucose analog and is transported into the cells through glucose transporters; thus, uptake of ^{18}F-FDG reflects an increased turnover of glucose. On the basis of this mechanism, it has been reported that vigorous muscle exercise, stress-induced muscle tension, and activities such as talking or chewing can cause a physiological increase in the uptake of ^{18}F-FDG in the muscles involved [18–22]. Based on these observations, it is thought that, in this case, the chronically stretched extensor muscles due to the kyphoscoliotic posture showed a pathological uptake of ^{18}F-FDG due to the increased muscle activity and that the increased uptake completely disappeared after the appropriate posture was acquired [11, 12]. This idea is compatible with the fact that each site in the paravertebral muscles

Fig. 1 A 60-year-old female with painful degenerative kyphoscoliosis. **a**, **b** Preoperative posterior-anterior and lateral plain radiographs of the whole spine showing degenerative kyphoscoliosis. **c** Lateral view of the preoperative maximum-intensity-projection image obtained by F-18-fluoro-2-deoxy-D-glucose positron-emission tomography/computed tomography (^{18}F-FDG-PET/CT) revealing abnormal uptake of FDG in the paravertebral muscles with normal distributions in the kidney and bladder. **d** Posterior-anterior view of the preoperative coronal ^{18}F-FDG-PET/CT image at the level of paravertebral and axial ^{18}F-FDG-PET/CT images at **e** L1/2 and **f** L3/4 levels, clearly showing that each uptake site is asymmetrical and coincides with the convex part of the respective curve of the lumbar spine (*white arrows*).**g**, **h** T2-weighted magnetic resonance imaging at the levels corresponding to **e** and **f**, respectively, showing no evidence of soft tissue metastasis. The white dotted lines in **d** indicate the level of each image of **e**, **g**, and **f**, **h**

showing increased uptake coincided with the convex part of each lumbar curve, because the paravertebral muscles are thought to be stretched most at this apex, where the rotation of the vertebra was also the most severe, causing three-dimensional elongation of the paravertebral muscles. As vertebral rotation is reported to be strongly correlated with pain in ASD patients, the pattern of the uptake of ^{18}F-FDG in this case was suggestive of an association with pain; however, further

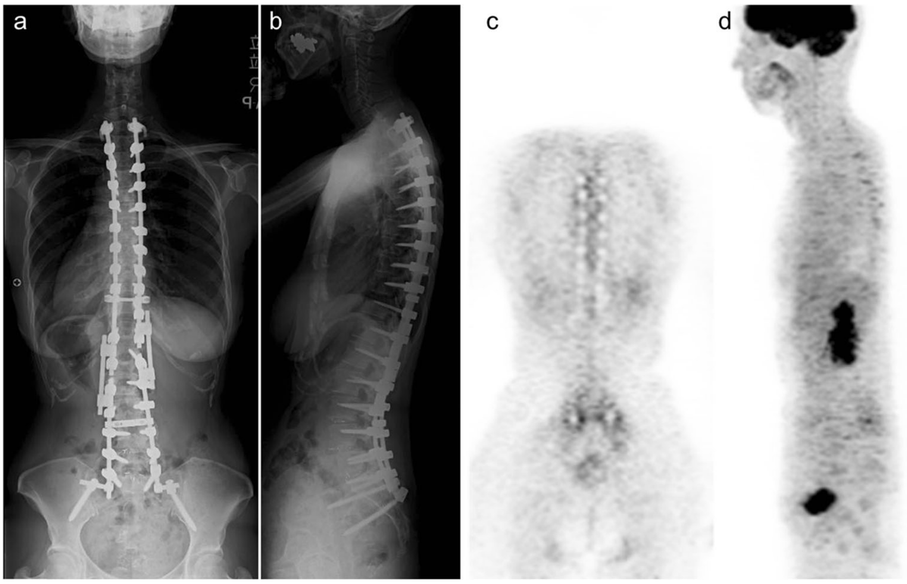

Fig. 2 **a**, **b** Posterior-anterior and lateral plain radiographs taken at 1 year after the revision surgery reveal that good spinal alignment has been achieved. **c**, **d** Posterior-anterior and lateral views of the maximum-intensity-projection images of ^{18}F-FDG-PET clearly show the disappearance of the abnormal uptake of FDG in the paravertebral muscles

investigation is required to determine whether this pathological uptake of ^{18}F-FDG in the paravertebral muscles reflects the pain experienced by ASD patients [23].

Some of the well-known factors causing LBP include intervertebral disc degeneration, facet joint arthritis, sacro-iliac joint dysfunction, and paravertebral muscle disorder. In this case, although the patient was receiving treatment for RA, arthritis of the facet joint or the sacro-iliac joint was not detected on ^{18}F-FDG-PET/CT. Furthermore, a high-intensity zone in the intervertebral discs, which is known to be correlated with LBP, was not seen on MRI. On the basis of these findings, the LBP in this case was considered to be caused by chronic fatigue in the paravertebral muscles, which was visualized with ^{18}F-FDG-PET/CT.

In conclusion, we present a case of painful degenerative kyphoscoliosis in which the paravertebral muscles at the convex region of the lumbar curves revealed an asymmetrically increased uptake of ^{18}F-FDG-PET/CT preoperatively. This study indicates the possibility of using ^{18}F-FDG-PET/CT to visualize the increased activity of painful paravertebral muscles in patients with ASD. Further investigation is mandatory to provide evidence of the usefulness of ^{18}F-FDG-PET/CT in the care and management of ASD patients.

Table 1 Results of the patient-oriented questionnaires

	Preoperative	Postoperative
NRS	8	0
RDQ	16 pts	0 pts
ODI	67 %	0 %

Each questionnaire was completed before the primary surgery and at 1 year after the revision surgery

NRS Numeric Rating Scale, *RDQ* Roland-Morris Disability Questionnaire, *ODI* Oswestry Disability Index

Compliance with ethical standards

Disclosure The authors declare that they have no conflict of interest concerning the materials or methods used in this study, or the findings specified in this paper.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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PLOS | ONE

RESEARCH ARTICLE

Psychometric Assessment of the Japanese Version of the Zurich Claudication Questionnaire (ZCQ): Reliability and Validity

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Abstract

Purpose

The Zurich Claudication Questionnaire (ZCQ) is a self-administered measure to evaluate symptom severity, physical function, and surgery satisfaction in lumbar spinal stenosis (LSS). The purpose of this study is to assess the psychometric properties of the Japanese ZCQ in LSS patients.

Methods

LSS patients who are scheduled to undergo surgery were recruited from 12 facilities. Responses to several questionnaires, including the Japanese ZCQ; the visual analogue scale (VAS) to evaluate the degree of pain in the buttocks/legs, numbness in the buttocks/legs, and low back pain; the Oswestry Disability Index (ODI); and the SF-36v2, were collected before surgery and again 3 months after surgery (the post-surgery ZCQ was administered twice for test-retest reliability). For reliability, test-retest reliability was evaluated using the intra-class coefficient (ICC) and internal consistency was evaluated using Cronbach's alpha coefficient. Concurrent validity was assessed using Spearman's correlation

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coefficients between the Japanese ZCQ and other questionnaires. Effect size (ES) and standard response mean were calculated for responsiveness. All analyses were performed individually for the Japanese ZCQ symptom, function, and satisfaction domains.

Results

Data from 180 LSS patients were used in this analysis. The ICCs were 0.81, 0.89, and 0.88 and Cronbach's alpha coefficients were 0.78, 0.84, and 0.92 for the Japanese ZCQ symptom, function, and satisfaction domains, respectively. Regarding the concurrent validity, strong correlations (±0.5) were demonstrated between the Japanese ZCQ domains and the VAS leg pain, ODI, and SF-36v2 physical functioning or bodily pain, whereas correlations were approximately 0.3 in scales measuring other symptoms that are less related to symptom, function, or satisfaction domains. ESs showed high values for the ZCQ symptom and function domains (-1.73 for both).

Conclusions

These psychometric assessments demonstrate that the Japanese ZCQ is a psychometrically reliable and valid measure in LSS. The Japanese ZCQ can evaluate both multi-dimensional aspects and the level of surgery satisfaction.

Introduction

Lumbar spinal stenosis (LSS) is a degenerative disorder that is characterized by a narrowing of the lumbar spinal canal, which entraps and compresses intraspinal vascular and nerve structures [1]. LSS results in neurological symptoms in the lower extremities, such as leg pain/numbness and gait disturbance, that dramatically deteriorate the patients' quality of life [2–4]. Conservative therapy is the primary treatment for LSS, and surgery is considered for LSS patients who do not improve [5]. Because pain or numbness is the primary complaint in LSS, the patient outcome measures have an important role in evaluating the treatment outcome.

Various outcome measures, such as the visual analogue scale (VAS) and Oswestry Disability Index (ODI) [6, 7], are used in research on LSS patients, but these measures are not disease specific. The Zurich Claudication Questionnaire (ZCQ), which is also known as both the Swiss Spinal Stenosis Measure and the Brigham Spinal Stenosis Questionnaire, was developed as a self-administered measure to assess symptom severity, physical function, and surgery satisfaction in LSS patients [8]. The questionnaire consists of three domains and uses a Likert-type scale. It includes 7 items for symptom severity with scores of 1 to 5, 5 items for functional disability with scores of 1 to 4, and 6 items for treatment satisfaction with score of 1 to 4. Higher scores indicate more severe LSS. The ZCQ demonstrates good validity and reliability in patients with LSS and is recommended as one of the appropriate methods for evaluating LSS treatment outcomes [9]. The ZCQ has been used worldwide in many studies on LSS [10–12].

To allow the use of the ZCQ in Japan, the English version was translated and linguistically validated as the Japanese ZCQ [13] following international guidelines [14, 15], but the psychometric validation has not yet been conducted.

The purpose of this study is to assess the psychometric properties of the Japanese ZCQ in LSS patients.

Materials and Methods

The study was approved by the Ethics Committee at the University of Tokyo. All patients who were enrolled in the study had provided written informed consent.

Participants

LSS patients between 20 and 85 years of age who were scheduled to undergo surgery were recruited. The inclusion criteria were as follows: 1) the presence of neurogenic intermittent claudication caused by numbness and/or pain in the lower limbs and 2) magnetic resonance imaging-confirmed symptomatic LSS that might explain the patient's symptoms. The exclusion criteria were as follows: 1) a positive straight leg raising test result (sciatic pain at < 70 degrees of leg elevation), which indicates that the pain is likely to be due to lumbar disc herniation; 2) presentation with lower-extremity peripheral arterial disease; 3) a history of spinal surgery; 4) complications causing disorders that interfere with gait, such as myelopathy; 5) peripheral neuropathy, such as diabetic neuropathy of the leg; or 6) disorders that potentially hinder gait other than LSS (e.g., rheumatoid arthritis). The study was conducted in 2010 at the University of Tokyo and 11 affiliated facilities, all of which are located in or near Tokyo.

Measures

Questionnaires were administered a maximum of 3 times: 1) before surgery, 2) 3 months after surgery, and 3) a few weeks after the second questionnaire if symptoms had not changed. The questionnaires administered before and 3 months after surgery included the Japanese versions of the ZCQ, ODI [6, 7], VAS for back/leg pain and leg numbness, and the SF-36 Ver.2 (SF-36v2). The ODI is a principal, condition-specific outcome measure used to assess disability from spinal disorders, particularly low back pain (LBP). The ODI consists of 10 items: pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and traveling. Each item is scored on a 6-point Likert-type scale with scores ranging from 0 to 5, and a higher score indicates a more severe disability. The reliability and validity of the Japanese version of the ODI were previously confirmed [16].

The degree of pain associated with buttock/leg pain or LBP was measured using a VAS covering the week prior to the relevant visit. We included three items: the degree of pain in the buttocks/legs, the degree of numbness in the buttocks/legs, and the degree of LBP. The scale ranged from 0 (no pain at all) to 10 (the worst pain/numbness imaginable).

The SF-36v2 is a questionnaire containing 36 items to assess the general health-related quality of life (QOL) [17]. The items are categorized into 8 domains: physical function, role limitations-physical, vitality, general health perception, bodily pain, social function, role limitations-emotional, and mental health. Each domain is scored from 0 to 100, with a higher score indicating a better QOL. A Japanese version of the SF-36v2, which has demonstrated good reliability and validity, was used in this study [18, 19].

Statistical analysis

Demographic and clinical characteristics of the participants were analysed descriptively. The Japanese ZCQ domain scores were summarized to examine missing data and the distribution. The scoring for each domain was carried out in the same way it would be for the English version of the ZCQ [8].

Psychometric properties of the Japanese ZCQ were assessed by evaluating reliability and validity. Responsiveness was also assessed. Reliability was evaluated by test-retest reliability and internal consistency. For test-retest reliability, the extent of agreement between two time points was examined using the intra-class correlation coefficient (ICC) in patients with stable symptoms after spine surgery. The coefficient ranged from 0 to 1, with a higher value showing increased reliability. A coefficient greater than or equal to 0.7 was considered sufficient to determine test-retest reliability [20].

For internal consistency, the homogeneity of the items within the domain was evaluated using Cronbach's alpha coefficients of the pre-surgery responses for the symptom and function domains and of the post-surgery responses for the satisfaction domain. A Cronbach's alpha of 0.7 or higher was considered acceptable for internal consistency, while a score above 0.8 was good and above 0.9 was excellent [21].

For concurrent validity, the degree of correlation with the external criteria (ODI, VAS, and SF-36v2) was assessed using Spearman's correlation coefficient of the pre-surgery responses for the symptom and function domains and of the post-surgery responses for the satisfaction domain. Scales measuring similar concepts were expected to show a moderate to strong correlation, while those measuring different concepts were expected to show a weak correlation. For example, the VASs of pain in the buttocks/legs and numbness in the buttocks/legs were expected to correlate strongly with the Japanese ZCQ symptom domain, the ODI with the ZCQ function domain, and the SF-36v2 social functioning or vitality with the ZCQ satisfaction domain. The correlation coefficient was interpreted as follows: ±0.1 was considered weak, ±0.3 was considered moderate, and ±0.5 was considered to be a strong correlation [21].

Responsiveness was evaluated by the effect sizes (ESs) and standard response means (SRMs). The ES was obtained by calculating the mean change in scores from before to 3 months after surgery divided by the standard deviation of the pre-surgery score. An ES of 0.2 was considered small, 0.5 was moderate and 0.8 was large, following the guidelines proposed by Cohen [22]. The SRM was obtained by the mean change in scores from before to 3 months after surgery divided by the standard deviation of the mean change. The higher the ES or SRM, the greater was the level of sensitivity to detect change.

All statistical tests were two sided with a significance level of 5%. All analyses were performed using SAS release 9.3 (SAS Institute, Cary, NC, USA).

Results

Patient characteristics

A total of 195 participants were recruited for this study. Of those, 180 took part in the first questionnaire administration before surgery, and 135 provided answers after surgery. Demographic and clinical characteristics of the recruited patients at pre-surgery are summarized in Table 1. The mean (standard deviation, SD) age was 68.2 (9.9) years, and 57.8% of the patients were male. The mean (SD) duration of LSS was approximately 3.7 (4.6) years. Types of symptom and surgery were evenly distributed. Approximately half the patients had spondylosis, followed by degenerative spondylolisthesis as the second most common diagnosis.

The symptom, function, and satisfaction scores at pre- and post-surgery are summarized in Table 2. The mean and median were similar in all 3 domains at both time points. The mean or median scores of the symptom and function domains at 3 months after surgery are smaller than at pre-surgery.

Reliability

To analyse test-retest reliability, 30 participants who underwent surgery and answered the Japanese ZCQ twice were selected. The ICCs for the Japanese ZCQ symptom, function, and satisfaction domains were 0.81, 0.89, and 0.88, respectively.

Table 1. Demographic and clinical characteristics of the lumber spinal stenosis patients (n = 195).

Characteristics	n (%) or mean (SD)
Age (years)	68.2 (9.9)
Sex	
Male	111 (57.8)
Female	81 (42.2)
Disease duration (months)	43.9 (55.7)
Types of symptom	
Nerve root	56 (29.3)
Cauda equine	65 (34.0)
Mixed	70 (36.7)
Surgery type	
Decompression only	92 (47.2)
Decompression and fusion	103 (52.8)
Types of lumber spinal stenosis	
Spondylosis	98 (50.8)
Degenerative spondylolisthesis	73 (37.8)
Degenerative scoliosis	18 (9.3)
Isthmic spondylolisthesis	4 (2.1)
Working status	
At work	65 (33.7)
Out of work	128 (66.3)
Smoking	
Smokers	47 (24.2)
Non-smokers	147 (75.8)

Values are n (%) or mean (SD).
Not all groups above total 195 because some of the characteristics had missing values.

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The internal consistency was evaluated using the data collected from patients who replied to the Japanese ZCQ at pre-surgery for the symptom and function domains and at post-surgery for the satisfaction domain. Cronbach's alpha coefficients for the Japanese ZCQ symptom, function, and satisfaction domains were 0.78, 0.84, and 0.92, respectively.

Validity

To assess the concurrent validity, the correlation coefficients between the 3 domains of the Japanese ZCQ and the external criteria (VAS, ODI, and SF-36v2) were calculated (Table 3). All 3

Table 2. Distribution of the Zurich Claudication Questionnaire (ZCQ) subscales.

ZCQ Subscale	Pre-surgery (n = 180)*		3 months after surgery (n = 135)*	
	Mean (SD)	Median (minimum, maximum)	Mean (SD)	Median (minimum, maximum)
Symptom	3.41 ± 0.67	3.43 (1.57, 5.00)	2.25 ± 0.75	2.14 (1.00, 4.71)
Function	2.70 ± 0.57	2.80 (1.00, 3.75)	1.71 ± 0.66	1.50 (1.00, 3.60)
Satisfaction	–	–	1.97 ± 0.72	1.83 (1.00, 4.00)

Response of satisfaction was not obtained at pre-surgery. SD: Standard Deviation
*: Due to missing responses, domain scores for the symptom and function domains at 3 months after surgery could not be computed for one patient, and domain scores for the satisfaction domain at 3 months after surgery could not be computed for 2 patients.

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Table 3. Spearman's correlation coefficients (95% confidence interval) between the ZCQ and the ODI, VAS, and SF-36v2.

Measure	ZCQ Symptom (n = 180)	ZCQ Function (n = 180)	ZCQ Satisfaction (n = 135)
ZCQ symptom	–	0.63 (0.53, 0.71)	0.79 (0.72, 0.85)
ZCQ function	0.63 (0.53, 0.71)	–	0.73 (0.63, 0.80)
ZCQ satisfaction	–	–	–
VAS leg pain	0.50 (0.38, 0.60)	0.50 (0.38, 0.61)	0.73 (0.63, 0.80)
VAS leg numbness	0.58 (0.46, 0.67)	0.49 (0.36, 0.60)	0.67 (0.56, 0.76)
VAS low back pain	0.48 (0.35, 0.59)	0.42 (0.29, 0.54)	0.58 (0.44, 0.69)
ODI	0.63 (0.53, 0.71)	0.75 (0.67, 0.80)	0.74 (0.65, 0.80)
SF-36 physical functioning	-0.56 (-0.66, -0.45)	-0.62 (-0.70, -0.52)	-0.62 (-0.71, -0.50)
SF-36 role limitations-physical	-0.46 (-0.57, -0.34)	-0.51 (-0.61, -0.39)	-0.57 (-0.68, -0.44)
SF-36 bodily pain	-0.59 (-0.68, -0.48)	-0.63 (-0.71, -0.53)	-0.65 (-0.73, -0.53)
SF-36 social functioning	-0.44 (-0.55, -0.31)	-0.38 (-0.50, -0.24)	-0.61 (-0.71, -0.49)
SF-36 general health	-0.31 (-0.43, -0.17)	-0.28 (-0.41, -0.14)	-0.56 (-0.67, -0.43)
SF-36 vitality	-0.35 (-0.47, -0.21)	-0.41 (-0.52, -0.28)	-0.59 (-0.69, -0.46)
SF-36 role limitations-emotional	-0.46 (-0.57, -0.33)	-0.50 (-0.60, -0.38)	-0.50 (-0.61, -0.35)
SF-36 mental health	-0.31 (-0.44, -0.17)	-0.33 (-0.45, -0.19)	-0.54 (-0.65, -0.41)

Calculations of the ZCQ symptom and function domains were performed with the ZCQ responses at pre-surgery and those of the ZCQ satisfaction domain at 3 months after surgery.

95% Confidence interval is shown as lower and upper values. $P < 0.0001$ for all.

ZCQ, Zurich Claudication Questionnaire; ODI, Oswestry Disability Index; VAS, Visual Analogue Scale; SF-36, 36-Item Short-Form Health Survey Ver. 2.

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domains of the Japanese ZCQ correlated well with one another. Strong correlations with all 3 domains were observed in VAS leg pain by values of approximately 0.50–0.73, in ODI (0.63–0.75), and in physical functioning (-0.56–0.62) or bodily pain (-0.59–0.65) in the SF-36v2. Regarding the VAS, the coefficients of leg pain or leg numbness were generally higher than for the low back pain in all 3 Japanese ZCQ domains. With regard to each domain on the SF-36v2, strong correlations were observed between the Japanese ZCQ symptom domain and bodily pain or physical functioning; the ZCQ function domain and physical functioning, role limitations-physical, bodily pain, or role limitations-emotional; and the ZCQ satisfaction domain and all 8 SF-36v2 domains. Overall, all three Japanese ZCQ domains were correlated to all external criteria to a moderate to strong degree. However, all of the correlations between the Japanese symptom and function domains and the general health and mental health of the SF-36v2 were smaller: approximately 0.3.

Responsiveness

To assess the responsiveness, the ESs between the Japanese ZCQ and external criteria (ODI, VAS, and SF-36v2) were calculated (Table 4). The ES was highest in the Japanese ZCQ function domain and symptom domain, followed by VAS leg pain, SF-36v2 bodily pain, VAS leg numbness, ODI, and VAS LBP, which were all above 0.8. Japanese ZCQ symptom and function domains had the two highest SRMs among the measures in this study (1.54 and 1.38, respectively).

Discussion

The Japanese ZCQ was translated and linguistically validated prior to this study [13]. As a next step for developing a valid and reliable measure, the psychometric properties of the ZCQ were

Table 4. Responsiveness of outcome measures in the study.

Measure	Change at 3 months after surgery from before surgery		ES	SRM
	mean	SD		
ZCQ symptom	-1.16	0.75	-1.73	-1.54
ZCQ function	-1.01	0.71	-1.73	-1.38
ODI	-22.69	18.61	-1.22	-1.20
VAS leg pain	-3.86	3.41	-1.64	-1.20
VAS leg numbness	-3.37	2.98	-1.28	-1.20
VAS low back pain	-3.35	3.24	-1.15	-1.02
SF-36 physical functioning	12.98	16.89	0.74	0.83
SF-36 role limitations-physical	6.56	18.28	0.44	0.39
SF-36 bodily pain	12.52	13.34	1.44	0.91
SF-36 social functioning	6.14	18.61	0.40	0.36
SF-36 general health	4.40	8.08	0.45	0.52
SF-36 vitality	8.79	12.36	0.72	0.68
SF-36 role limitations-emotional	6.75	20.41	0.42	0.35
SF-36 mental health	7.38	14.03	0.54	0.52

Responsiveness of the ZCQ satisfaction domain was not calculated because a response on satisfaction was not obtained prior to surgery.

SD, Standard Deviation; ES, Effect Size; SRM, Standard Response Mean; ZCQ, Zurich Claudication Questionnaire; ODI, Oswestry Disability Index; VAS, Visual Analogue Scale; SF-36, 36-Item Short-Form Health Survey Ver. 2.

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assessed using the data collected from Japanese LSS patients. Based on the results of the current assessments, the Japanese ZCQ shows good validity and reliability. The responsiveness is also shown to be specific to LSS compared to other measures, such as the ODI or SF-36v2.

The ICCs for the 3 Japanese ZCQ domains (symptom, function, and surgery satisfaction) all satisfied the level of 0.7. The ICC was highest in the function domain and lowest in the symptom domain, but all were approximately 0.9. We set a satisfactory level of 0.7 for research use, but an ICC higher than 0.9 could be considered satisfactory for clinical practice in test-retest reliability [20, 21]. The ICC range was similar to other language versions, such as the original English (0.92), Norwegian (0.89–0.92), and simplified Chinese (0.91–0.95) versions [8, 23, 24].

Cronbach's alpha coefficients showed good to excellent levels of internal consistency for all 3 domains, and these were approximately 0.9 in the function and surgery satisfaction domains. Although a Cronbach's alpha of 0.7 is considered satisfactory for psychometric assessments, in clinical practice, values above 0.9 are considered suitable [20, 21]. Therefore, this measure is sufficient for application in clinical practice. Moreover, the range of Cronbach's alpha coefficients was similar to that in other language versions, including the original English (0.84–0.89), Norwegian (0.94–0.96), Iranian (0.88), and simplified Chinese (0.86–0.91) versions [8, 23–25]. On the basis of these reliability results, the Japanese ZCQ showed sufficient reliability.

The concurrent validity assessment showed moderate to strong agreement with the external criteria (ODI, VAS, and 8 domains of the SF-36v2). Scales measuring similar concepts with each Japanese ZCQ domain showed moderate to strong correlations, such as the correlation between the ZCQ symptom domain and the bodily pain scale of the SF-36v2. Similar findings were also observed in the original English and simplified Chinese versions [8, 24]. All 3 Japanese ZCQ domains correlated strongly with one another, with the highest correlation observed between the symptom and satisfaction domains. By contrast, scales that measure different concepts showed smaller correlation coefficients, such as that between the Japanese ZCQ symptom and function domains and the general health scale of the SF-36v2. The correlation of the satisfaction domain was calculated using data obtained after surgery, when the mean changes in both symptom and function improved by a score of 1. This implies that patients in this study may have been satisfied when both their symptoms and function improved.

The Japanese ZCQ showed good responsiveness in both the symptom and function domains, and it showed better responsiveness than other measures, such as the ODI, which is commonly used to evaluate disability. The trend regarding responsiveness was similar to the results of other languages. For example, the ES and SRM of the symptom or function domain were between those of the original English (SRM = 1.48 and 1.6 in patients who were satisfied with surgery) and Norwegian (ES = 1.9 and 1.2) versions [23]. The current results showed that Japanese ZCQ symptom and function domains reflect changes in the post-operative condition of LSS in Japanese patients with a high degree of sensitivity. Because this measure can be used for multi-dimensional evaluations, is LSS specific, and has advantages in its simplicity and easy-to-answer format, the Japanese ZCQ may be useful for the elderly, who make up the majority of LSS patients. In addition, this questionnaire may enable better communication between the physician and the patient because sharing the responses of the patients evaluated in this study may enhance patient compliance with treatments.

There are several limitations of this study that should be mentioned. This study was carried out in Tokyo and its outlying areas. Because more than 10% of the Japanese population resides in this area, the study may over-represent the urban Japanese population. Therefore, we should consider the population of other suburban areas in Japan. Second, some physicians might have asked patients to complete the questionnaire in front of them and seen the responses the patients selected. This may have resulted in a bias in the responses being close to physicians' expectations. Third, we did not assess known-group validity; i.e., score changes between the groups in terms of severity. However, we were able to show good responsiveness of the symptom and function domains in this study. Lastly, the presence of dynamic instability was not assessed in this study, although it plays an important role in the decision of treatment/surgery in a clinical setting. Patients' responses to the questionnaire might have been influenced by the types of surgery/treatment; however, as this was a psychometric assessment study of the Japanese ZCQ, which will be widely used in patients with LSS, we consider that it is not a methodological problem to include patients with LSS regardless of the presence of dynamic instability.

Conclusion

The current psychometric assessments have demonstrated that the Japanese ZCQ is psychometrically reliable and valid measure in LSS. The Japanese ZCQ, which includes symptom and function domains, can evaluate multi-dimensional aspects along with the level of surgery satisfaction.

Supporting Information

S1 File. Supporting information. Dataset of this study.
(XLS)

Author Contributions

Conceived and designed the experiments: NH K. Matsudaira. Performed the experiments: NH K. Matsudaira K. Masuda JT KT AK MM N. Kawamura KY ST SO HS JM KH SK KN HO. Analyzed the data: NH TS. Wrote the paper: KI N. Kikuchi K. Matsudaira.

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RESEARCH ARTICLE

The Association between the Cross-Sectional Area of the Dural Sac and Low Back Pain in a Large Population: The Wakayama Spine Study

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Abstract

Objective

The purpose of this study was to evaluate the relations between the degree of encroachment, measured as the cross-sectional area of the dural sac, and low back pain in a large population.

Methods

In this cross-sectional study, data from 802 participants (247 men, 555 women; mean age, 63.5 years) were analyzed. The measurement of the cross-sectional area of the dural sac from the level of L1/2 to L4/5 was taken using axial T2-weighted images. The minimum cross-sectional area was defined as the cross-sectional area of the dural sac at the most constricted level in the examined spine. Participants were divided into three groups according to minimum cross-sectional area measurement quartiles (less than the first quartile, between the first and third quartiles, and greater than the third quartile). A multivariate logistic regression analysis was used to estimate the association between the minimum cross-sectional area and the prevalence of low back pain.

Results

The mean minimum cross-sectional area was 117.3 mm^2 (men: 114.4 mm^2; women: 118.6 mm^2). A logistic regression analysis adjusted for age, sex, body mass index, and other

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Data Availability Statement: The present study used resident data from two communities in Wakayama prefecture. It is impossible for us to provide and upload these data in a public repository because we have confirmed with these municipalities and residents that data will remain confidential. We will provide anonymized data on request after discussing the contents with the municipalities, as long as researchers are qualified to request these data. Data requests can be made to the corresponding author at hashizum@wakayama-med.ac.jp

confounding factors, including disc degeneration, showed that a narrow minimum cross-sectional area (smaller than the first quartile) was significantly associated with low back pain (odds ratio, 1.78; 95% confidence interval, 1.13–2.80 compared to the wide minimum cross-sectional area group: minimum cross-sectional area greater than the third quartile measured).

Conclusion

This study showed that a narrow dural sac cross-sectional area was significantly associated with the presence of low back pain after adjustment for age, sex, and body mass index. Further investigations that include additional radiographic findings and psychological factors will continue to elucidate the causes of low back pain.

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Introduction

Low back pain (LBP) is a multifactorial symptom, a common cause of morbidity and disability, and was reported to have a prevalence of 28.5% in a recent study [1,2]. There are many causes of chronic LBP, one of which is lumbar spinal stenosis (LSS) [3]. According to the Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care developed by The North American Spine Society [4], degenerative LSS describes a condition in which there is diminished space available for the neural and vascular elements in the lumbar spine secondary to degenerative changes in the spinal canal. When symptomatic, this condition causes a variable clinical syndrome of gluteal and/or lower-extremity pain and/or fatigue, which may occur with or without back pain. In reality, however, 67.5%–95% of patients with LSS experience LBP [5–7].

LBP in patients with LSS is also multifactorial. Patients with LSS often have facet arthrosis and degenerative discs. These pathologies may explain their back pain. Earlier findings from preoperative imaging studies of patients with central spinal stenosis have suggested that the cross-sectional area (CSA) of the dural sac was closely related to preoperative walking ability, health-related quality of life, leg pain, and LBP [8–10]. Recent studies have also reported the possibility of improving LBP following decompression surgery [11,12]. Thus, it is possible that constriction of the dural sac is also the cause of LBP in LSS patients.

However, no research to date has focused on the association between the prevalence of LBP and the cross-sectional area of the dural sac in the general population. Thus, the purpose of this study was to evaluate the relations between the degree of encroachment, measured as the CSA of the dural sac, and LBP in a large population.

Methods

Study design

We performed a cross-sectional, population-based study.

Participants

The present study design was approved by the Wakayama Medical University Ethics Committee. All participants provided their written informed consent. The Wakayama Spine Study is a population-based study of degenerative spinal disease [13–17] conducted with a sub-cohort of the large-scale, population-based cohort study Research on Osteoarthritis/Osteoporosis against Disability (ROAD) [18,19]. ROAD is a nationwide, prospective study of bone and joint diseases consisting of population-based cohorts established in three communities in Japan. The participants were recruited from listings of resident registrations in three communities that have different characteristics: an urban region in I town, Tokyo; a mountainous region in H town, Wakayama; and a coastal region in T town Wakayama. The inclusion criteria, apart from residing in those communities, included the ability to walk to the survey site, to report data, and to understand and sign an informed consent form. No other exclusion criteria were used. A third visit of the ROAD study began in 2012 and was completed in 2013. From the volunteers participating in the third visit of the ROAD study, 1575 individuals (513 men, 1062 women), which included 718 individuals in the mountainous area and 857 individuals in the coastal area, were recruited to the second visit of the Wakayama Spine Study. Magnetic resonance imaging (MRI) was conducted only to the individuals in the coastal area because of the funding limitation. Thus, we evaluated data from 857 individuals in the coastal area for the present study. Among them, 42 participants with incomplete MRI records and one participant who had previously undergone posterior lumbar fusion were excluded from the analysis (Fig 1).

Experienced board-certified orthopedic surgeons also asked all participants the following question regarding LBP and buttock and leg pain: "Have you experienced LBP (or buttock and leg pain) on most days during the past month, in addition to now?" Those who answered "yes" were defined as having LBP (buttock and leg pain), based on previous studies [20–24]. Twelve participants who lacked information regarding LBP or buttock and leg pain were excluded. Thus, 802 participants (247 men and 555 women) ranging in age from 19 to 93 years (mean, 63.0 years for men and 63.8 years for women) were included for analysis (Fig 1). All study participants provided informed consent, and the study design was approved by the appropriate ethics review boards.

Magnetic resonance imaging

A mobile MRI unit (Achieva 1.5 T; Philips Medical Systems, Best, the Netherlands) was used, and whole-spine MRI was performed for all participants on the same day as the examination. The participants were supine during the MRI, and those with rounded backs used triangular pillows under their heads and knees. The imaging protocol included sagittal T2-weighted fast spin echo imaging (repetition time, 3,000 ms/echo; echo time, 120 ms; and field of view, 270 × 270 mm) and axial T2-weighted fast spin echo imaging (repetition time, 2,100 ms/echo; echo time, 100 ms; and field of view, 180 × 180 mm). Sagittal images were taken for the entire spine, but axial images were obtained for each lumbar intervertebral level (L1/2–L5/S1) parallel to the vertebral endplates.

The CSA of the dural sac

CSA measurement was performed with axial T2-weighted images using a radiological workstation specially designed for such purposes. The CSA of the lumbar dural sac, defined as the area occupied by the dural sac at the disc level, was measured from the level of L1/2 to L4/5 (Fig 2). The measurement was performed by an orthopedic surgeon who was blinded to the background of the participants. The CSA of the dural sac at the most constricted level in the examined spine was called the minimum CSA (mCSA) [8]. The participants were divided into three groups according to quartiles (the narrow group: mCSA less than the first quartile [Q1] measurement; the middle group: mCSA between the Q1 and the third quartile [Q3] measurements; and the wide group: mCSA greater than the measurement for Q3).

Disc degeneration

Disc degeneration (DD) grading was performed by a board-certified orthopedic surgeon who was blinded to the background of the participants, in accordance with previous studies. The

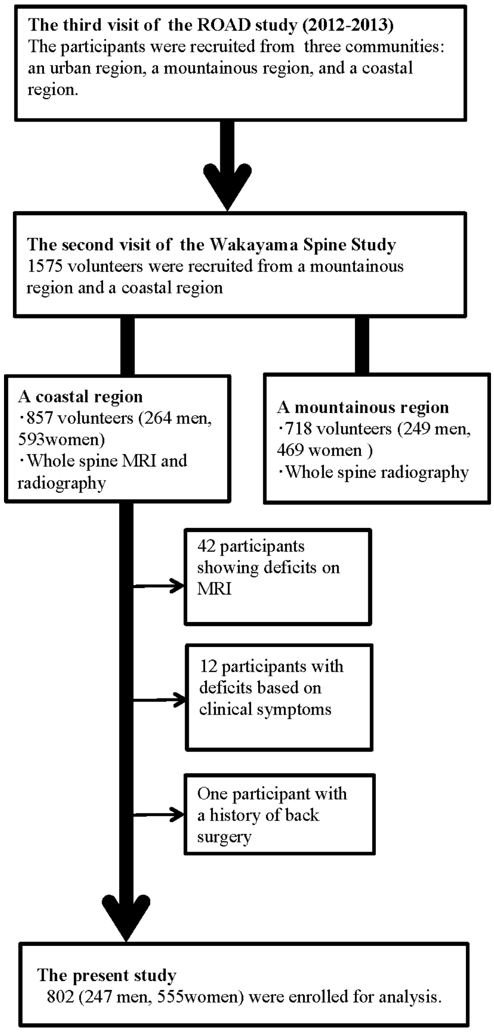

Fig 1. Flow diagram depicting participants recruited to the present study from the third visit of the ROAD study.

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degree of DD on MRI was classified into five grades based on the Pfirrmann classification system [25], with grades 4 and 5 indicating DD.

The signal intensity for grade 4 was intermediate to hypointense for the cerebrospinal fluid (dark gray), while the structure was inhomogeneous. Meanwhile, for grade 5, the signal intensity was hypointense for the cerebrospinal fluid (black), and the structure was likewise inhomogeneous. In addition, the disc space was collapsed

Statistical analysis

Radiographic changes were compared between sexes using the chi-squared test. The Jonckheere-Terpstra test was used to identify trends with regard to age or spinal levels for the CSA of dural sac. To test the association between the presence of LBP and mCSA, we used the Cochran-Armitage test and multiple logistic regression analysis. In the regression analysis, we used the presence or absence of LBP as the objective variable and mCSA (the wide group vs.

Fig 2. Illustration of the dural sac cross-sectional area measurement technique.

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the narrow group; the wide group vs. the middle group) and the presence or absence of DD and buttock and leg pain as explanatory variables, in addition to basic characteristics, such as age, sex, and body mass index (BMI). Receiver operator characteristic (ROC) curves and the corresponding areas under the curve (AUCs) were used to evaluate how the prediction model performed on the test data. The AUC was also calculated independently for the factors in the final model to demonstrate the additional value gained from the addition of each factor to the model. ROC curves plot the true-positive rate (sensitivity) vs the false-positive rate (1-specificity). All statistical analyses except Jonckheere-Terpstra test were performed using JMP, version 8 (SAS Institute Japan, Tokyo, Japan). The Jonckheere-Terpstra test was performed using SPSS statistics 23 (IBM Japan, Tokyo, Japan).

Results

Table 1 shows the characteristics of the 802 participants in the present study, including age, demographic measurements, and symptoms. The prevalence of LBP and buttock and leg pain was 38.6% and 23.3%, respectively. The mean mCSA was 117.3 mm^2 (men: 114.4 mm^2, women: 118.6 mm^2). Q1 and Q3 values for mCSA for the group overall were 85.8 mm^2 and

Table 1. Characteristics of participants.

	Overall	Men	Women
No. of participants	**802**	**247**	**555**
Demographic characteristics			
Age (years)	63.5±13.1	63.0±13.9	63.8±12.7
Height (cm)	157.4±8.9	166.8±6.8	153.4±6.4
Weight (kg)	57.3±11.4	66.7±10.8	53.0±8.9
Body mass index (kg/m^2)	23.0±3.6	24.0±3.5	22.6±3.6
Symptom			
Low back pain	309(38.6%)	94(38.2%)	215(38.7%)
Buttock and leg pain	186(23.3%)	47(19.1%)	139(25.0%)

Data are presented as means ± standard deviation or as n (%).

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147.2 mm², respectively. The proportion of each group divided into quartiles based on the mCSA values among the 802 participants was as follows: for men, 30.0% for the narrow group (mCSA $\leq$ Q1), 48.2% for the middle group (Q1 $<$ mCSA $\leq$ Q3), and 21.8% for the wide group (Q3 $<$ mCSA), and for women, 22.9% for the narrow group, 50.8% for the middle group, and 26.3% for the wide group. The proportion of men in the narrow group was significantly higher than the proportion of women in the narrow group (p = 0.032). The prevalence of disc degeneration in the 802 participants was 91.4% (men: 91.1%, women: 91.5%). There were no significant differences for the prevalence of DD between men and women.

Table 2 summarizes the distribution of the CSA of the dura of the 802 participants in the present study. A Jonckheere-Terpstra test for ordered alternatives showed that there was a statistically significant trend of smaller median CSAs with higher age strata at all intervertebral levels from L1/2 to L4/5 in both genders ($p < 0.0005$). The CSAs had a tendency to decrease with lower intervertebral levels in both genders ($p < 0.0005$).

On analyzing the relationship between the prevalence of LBP and mCSA, we found that the prevalence of LBP increased as mCSA decreased. The prevalence of LBP was 50.3% for the narrow group, 36.6% for the middle group, and 30.8% for the wide group. The participants who had narrower mCSA values were more likely to have LBP ($p < 0.0001$).

Logistic regression analyses were performed with LBP as the objective variable, mCSA as the explanatory variable, and patient characteristics, including age, sex, and BMI, as potential risk factors (model 1). Belonging to the middle group (Q1 $<$ mCSA $\leq$ Q3) was not significantly associated with LBP (odds ratio, [OR] 1.26; 95% confidence interval [CI], 0.87–1.82). On the other hand, belonging to the narrow group (mCSA $\leq$ Q1) was significantly associated with LBP (OR, 1.97; 95% CI, 1.27–3.04).

We then added the presence of DD as a dependent variable (model 2). Belonging to the middle group (Q1 $<$ mCSA $\leq$ Q3) was not significantly associated with LBP (OR, 1.19; 95% CI, 0.82–1.74). In contrast, belonging to the narrow group (mCSA $\leq$ Q1) was significantly associated with LBP (OR, 1.94; 95% CI, 1.25–3.02).

Finally, the presence of buttock and leg pain was added as a dependent variable (model 3). Belonging to the middle group (Q1 $<$ mCSA $\leq$ Q3) was not significantly associated with LBP (OR, 1.18; 95% CI, 0.80–1.73); however, belonging to the narrow group (mCSA $\leq$ Q1) was significantly associated with LBP (OR, 1.78; 95% CI, 1.13–2.80). The results of the logistic regression analysis for all models are summarized in Table 3.

Fig 3 shows the receiver operating characteristic (ROC) curves for the multiple logistic regression models for LBP. The AUC for model 1 was 0.59; for model 2, 0.60; and for model 3,

Table 2. Distribution of cross sectional area of dura (mm²).

Men	Total	<50	50–59	60–69	70–79	≧80	Standardized Test Statistic	p-value
L1/2	172[149–192]	192[174–212]	177[154–193]	170[147–189]	154[132–181]	157[147–186]	-4.619	<0.0005
L2/3	146[120–172]	176[151–187]	157[136–174]	143[117–163]	126[107–158]	142[109–165]	-5.246	<0.0005
L3/4	132[102–165]	164 [146–181]	144[122–178]	122[102–149]	114[86–140]	119[88–137]	-5.652	<0.0005
L4/5	129[91–168]	166 [128–198]	140[111–186]	120 [88–157]	113[90–146]	99[73–154]	-5.538	<0.0005
Women	**Total**	**<50**	**50–59**	**60–69**	**70–79**	**≧80**	**Standardized Test Statistic**	**p-value**
L1/2	177[157–202]	204[176–220]	186[165–205]	176[156–199]	165[147–189]	168[145–191]	-7.506	<0.0005
L2/3	158[133–184]	188[168–210]	170[147–190]	153[130–178]	145[123–169]	148[112–161]	-8.915	<0.0005
L3/4	139[109–174]	179[149–197]	154[126–177]	134[107–163]	126[97–163]	113[73–153]	-8.775	<0.0005
L4/5	127[96–166]	149[111–189]	140[109–166]	123[96–157]	112[83–160]	107[77–141]	-6.003	<0.0005

Values are the median [first quartile- third quartile].

The CSAs had a tendency to decrease with age and lower intervertebral levels in both genders (Jonckheere-Terpestra test; p< 0.0005).

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Table 3. Association between low back pain and the minimum cross-sectional area in each logistic regression model.

	Explanatory variables	Category	OR	95%CI	AUC
model 1	mCSA	mCSA<Q1 vs. mCSA>Q3	2.02	1.30–3.12	0.59
		Q1≦mCSA<Q3 vs. mCSA>Q3	1.26	0.87–1.82	
model 2	mCSA	mCSA<Q1 vs. mCSA>Q3	1.94	1.25–3.02	0.6
		Q1≦mCSA<Q3 vs. mCSA>Q3	1.2	0.82–1.74	
	DD	1:presence 0:absence	2.41	1.23–4.73	
model 3	mCSA	mCSA<Q1 vs. mCSA>Q3	1.78	1.13–2.81	0.66
		Q1≦mCSA<Q3 vs. mCSA>Q3	1.18	0.80–1.73	
	DD	1:presence 0:absence	2.38	1.20–4.72	
	buttock and leg pain	1:presence 0:absence	3.31	2.33–4.69	

CI, confidence interval; DD, disc degeneration; mCSA, minimum cross-sectional area; OR, odds ratio; Q1, the first quartile; Q3, the third quartile; AUC, areas under the curve

Note: Multivariate logistic regression analysis of mCSA was associated with low back pain after adjustment for age, body mass index, and sex in each model. The minimum cross-sectional area of the dural sac is the cross-sectional area of the dural sac at the most constricted level in the examined spine from the level of L1/2 to L4/5. Q1, 85.8 mm2; median, 114.2 mm2; Q3, 147.2 mm

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0.66. The AUC for model 3 was significantly higher than those for the other two models (p = 0.0008).

Discussion

The purpose of this study was to evaluate the relations between the degree of encroachment, measured as the CSA of the dural sac, and LBP in a large population. In this study, narrowed dural sac CSA was significantly associated with the presence of LBP after adjustment for age, sex, and BMI. To the best of our knowledge, this is the first report of a positive association between LBP and the CSA of the dural sac in a large population of individuals ranging in age from 19 to 93 years old.

There are two possibilities to explain the narrow CSA of the dural sac. The narrow dural sac could be due to degenerative changes or to developmental stenosis of the dural sac. In this study, we considered that a narrow CSA of the dural sac was related to constriction of the dural sac due to degenerated tissue around the dural sac rather than to congenital stenosis, as 65.2%

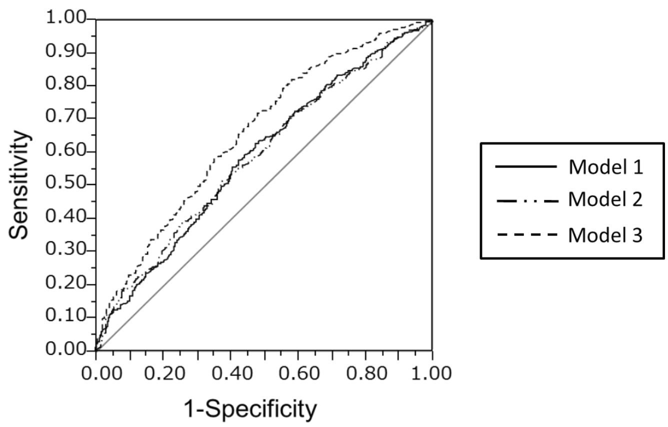

Fig 3. Receiver operating characteristic (ROC) curves for the multiple logistic regression models for low back pain. The area under the curve (AUC) for the ROC curves for models 1, 2, and 3 were 0.59, 0.60, and 0.66, respectively. The AUC for model 3 was significantly greater than the AUCs for models 1 and 2.

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of the participants were older than 60 years, and in fact, almost all patients with a small dural sac CSA had other degenerative findings, such as a bulging disc, thickened facet joint, and/or ligamentum flavum.

Findings from earlier preoperative imaging studies on patients with central spinal stenosis have suggested that the CSA of the dural sac was closely related to preoperative walking ability, health-related quality of life, leg pain, and LBP [8,10,26,27]. Moreover, it has been reported that LBP significantly improves following spinal decompression alone [12]. Jones et al. investigated Visual Analog Scale data for LBP in 119 patients with LSS, and they reported that there was a significant reduction in mean LBP from baseline to 6 weeks and 1 year postoperatively. Spinal decompression surgery has long been considered the gold standard surgical treatment for symptomatic LSS. The aim of decompression surgery is to improve radicular leg pain and walking distance. The authors concluded that there is a possibility for improvement in LBP after decompression surgery. We believe our current findings from an established, population-based cohort support the conclusions of the Jones et al. report. However, future studies are needed in order to identify patients who will show improvement in LBP after decompression surgery.

A potential explanation for LBP in LSS patients is the reduction in nutrient supply to ischemic nerves and hence the development of claudication pain originating from muscles supplied by the dorsal rami at the stenotic level [28]. Moreover, Konnai et al. reported that the lower lumbar dura mater is innervated by sensory nerves derived from upper lumbar dorsal root ganglia via the lumbar sympathetic trunk in rats. They concluded that these sensory nerves may mediate LBP and possibly interact with sympathetic nerves [29]. In LSS patients, the dural sac is encroached by degenerative tissue, such as a thickened ligamentum flavum, bulging disc, or osteophyte. Thus, sensory nerves innervating the dural sac can be pinched by degenerative tissues, which might cause LBP in LSS patients.

In the present study, disc degeneration was added as an objective variable to the multivariable regression model. As mentioned above, degenerative discs might be a potential source of LBP in LSS patients. Teraguchi et al. showed that there was a significant positive association between the presence of DD in the lumbar region and LBP [14]. According to that study, the presence of DD in the lumbar region was significantly associated with LBP. Thus, we added the presence of DD as an explanatory factor to adjust for the confounding effect of disc degeneration. Moreover, the presence of buttock and leg pain was added as a dependent variable to the multivariable regression model. LBP is defined as pain in the area bounded by the lowest palpable ribs superiorly and the gluteal folds inferiorly [30]. In this way, participants complaining of buttock pain due to radicular pain might be included in the group of patients with LBP. To adjust for the overlap, the presence of buttock and leg pain was also added as a dependent variable to the multivariable regression model. Finally, adjusting for buttock and leg pain would reinforce the hypothesis that LBP caused by constriction of the dural tube has a different pathology from that of radicular back pain.

After adding these two variables (DD, buttock and leg pain), a narrow CSA of the dural sac was still a significant variable associated with LBP. This result supports the hypothesis that a narrow CSA in the dural sac might be one of the reasons for LBP in LSS patients. Moreover, after adding DD and buttock and leg pain as dependent variables, the AUCs of the ROC curves for the multiple logistic regression analysis increased compared to the AUC before adding dependent variables. Adding the AUC for the ROC curve to the multiple logistic model after adding the presence of DD and buttock and leg pain was 0.66, which was not large. It is assumed that this small value indicates that the CSA of the dural sac might not be strongly correlated with LBP, because LBP can be caused by multiple factors, including osteoporosis, back muscle strain, poor alignment, and psychosocial difficulties. We could explain only a portion of the associated factors for LBP with one factor. However, adding some other factors to the models (MRI findings such as degenerative degeneration, or clinical findings such as buttock and leg pain) yielded a better multivariate model for LBP. Future investigations should include continued follow-up surveys of other factors, such as facet arthropathy or end-plate change, which would enable us to explain more about nonspecific low back pain.

The present study has several limitations. First, although more than 800 participants were included in the present study, the study population may not be representative of the general population because participants were recruited from only one area of Japan. Anthropometric measurements were compared between the participants of the present study and those of the general Japanese population [31]. There was a significant difference in BMI for both men and women in our study and that of the general population (BMI [standard deviation] in men: 24.0 kg/m^2 [3.5 kg/m^2] vs. 23.4 kg/m^2 [3.36 kg/m^2], respectively, p = 0.00; BMI [standard deviation] in women: 22.57 kg/m^2 [3.62 kg/m^2] vs. 22.29 kg/m^2 [3.69 kg/m^2], respectively, p = 0.031). Therefore, the participants included in this study might have had a different prevalence of LBP or leg pain. However, we believe that the association between the CSA of the dural tube and LBP, which was shown in this study, could be generalized. Second, this is a cross-sectional study, so any causal relationship between symptomatic LSS and physical performance cannot be clarified. The Wakayama Spine Study is a longitudinal survey, so further progress will help elucidate any causal relationships. Third, the configuration of the dural sac was not taken into account. Generally, stenosis of the lumbar spinal canal is divided into the following categories: central stenosis, lateral recess stenosis, and foraminal stenosis. A comprehensive evaluation of spinal stenosis that includes the presence of lateral recess stenosis or foraminal stenosis, and not just the CSA of the dural tube, would be more appropriate for predicting LBP. Finally, the cut-off values for the CSA of the dural sac also posed a problem. In this study, the first and third quartiles of the mCSA were used as the cut-off values for all levels. However, it is inevitable that two nerve roots depart from the cauda at each vertebral level. Thus, it is reasonable to assume a gradually decreasing cut-off value in the distal direction. It might be more appropriate to use different cut-off values for each intervertebral level.

LBP is caused by multiple factors beyond the scope of MRI findings. However, this study clarified that a narrowed CSA of the dural sac was associated with LBP. Although a narrowed CSA might not be strongly correlated with LBP, these findings contribute to our understanding of LBP. Further investigations along with continued follow-up surveys, including additional radiographic findings and psychological and social factors, including occupation, will continue to elucidate the causes of LBP.

Author Contributions

Conceived and designed the experiments: HI NY HH HO HY AM YN MY KM TA ST HK K. Nakamura.

Performed the experiments: HI NY HH HO KS YI K. Nagata MT RK SM.

Analyzed the data: HI NY HH HO.

Contributed reagents/materials/analysis tools: HI NY HH HO.

Wrote the paper: HI.

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Influence of work-related psychosocial factors on the prevalence of chronic pain and quality of life in patients with chronic pain

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ABSTRACT

Objectives: Working is a common cause of chronic pain for workers. However, most of them need to continue working despite the pain in order to make a living unless they get a sick leave or retirement. We hypothesised that the therapeutic effect of vocational rehabilitation may depend on psychosocial factors related to the workplace. To test this hypothesis, we examined the association of work-related psychosocial factors with the prevalence of chronic pain or health-related quality of life (HRQoL) among workers with chronic pain.

Methods: We examined 1764 workers aged 20–59 years in the pain-associated cross-sectional epidemiological survey in Japan. The outcomes were (1) chronic pain prevalence among all workers and (2) low Euro QoL (EQ-5D <0.76; mean value of the current study) prevalence among workers with chronic pain according to the degree of workplace social support and job satisfaction. Workplace social support and job satisfaction were measured using the Brief Job Stress Questionnaire. Multivariable-adjusted ORs were calculated using a logistic regression model including age, sex, smoking, exercise, sleep time, work hours, body mass index, personal consumption expenditure, intensity of pain and the presence of severe depressive symptoms.

Results: Chronic pain prevalence was higher among males reporting job dissatisfaction compared with those reporting job satisfaction. No difference was observed among women. Chronic pain prevalence did not differ between workers of either sex reporting poor workplace social support compared with those reporting sufficient support. Among workers with chronic pain, low HRQoL was more frequent in those reporting job dissatisfaction. Similarly, low HRQoL was more frequent in patients with chronic pain reporting poor social support from supervisors or co-workers compared with patients reporting sufficient support.

Conclusions: Work-related psychosocial factors are critical for HRQoL in patients with chronic pain.

Strengths and limitations of this study

- Our study included a large population and used the specialised questionnaire for pain medicine.
- This is the first study to investigate the association between work-related psychosocial factors and health-related quality of life of patients with chronic pain.
- Our questionnaire included only three psychosocial factors: social support from supervisors, support from co-workers and job satisfaction.
- Patients with severe chronic pain who took sick leave or had retired because of pain were not included in our study.

INTRODUCTION

The existence of chronic pain among workers is an economic burden and major public health problem.[1] Although most workers need to continue their work despite pain, in order to make a living, unless they get sick leave or retire, workers with chronic pain are likely to have lower productivity. Physical and mental overwork can cause chronic pain, which, according to the classical rehabilitation model, requires rest for relief and remission.[2] In contrast, the recent vocational rehabilitation model recommends continuing work or prompt return as soon as possible based on studies showing the benefits of remaining active despite pain.[2–4] However, patients with chronic pain may require added motivation or appropriate accommodation; thus, success of vocational rehabilitation may depend on psychosocial factors related to the workplace environment.

Poor work-related psychosocial factors were associated with a higher chronic pain prevalence among European and North American workers,[2 5 6] but these relationships have not been examined among Asian workers. Workplace environments vary among cultures; therefore, the influence of psychosocial factors on chronic pain may also differ in Asia.[7]

Health-related quality of life (HRQoL) measures are frequently used in epidemiology to quantify general health and functional status. Furthermore, HRQoL has been associated with worker productivity and is often used to calculate the cost-effectiveness of healthcare programmes.[8] Thus, HRQoL is an appropriate metric to evaluate the effects of work-related psychosocial factors on workers with health problems, but the relationship between work-related psychosocial factors and HRQoL of patients with chronic pain has not been explored.

Thus, we analysed the association between work-related psychosocial factors and chronic pain prevalence in the Japanese workplace. In addition, we examined the association between work-related psychosocial factors and HRQoL among patients with chronic pain.

MATERIALS AND METHODS

Study population

The pain-associated cross-sectional epidemiological study was an internet survey (conducted from 10 to 18 January 2009) designed to evaluate pain in a large Japanese population, using a self-reported questionnaire.[9] The sampling procedure ending in the sample being analysed in the current study is shown in figure 1. A total of 20 044 respondents (9746 men and 10 298 women) aged 20–79 years, matching the Japanese demographic composition in 2007,[10] were recruited by email from 1 477 585 candidates who registered with an internet survey company (Rakuten Research Inc, Tokyo, Japan).[11] Invitation emails containing a link to the first questionnaire were sent by computer system until the targeted sample number was achieved. Incomplete questionnaires were rejected automatically, so the response rate was not calculated. The first questionnaire included items on age, sex, job, HRQoL and pain. Subsequently, detailed questionnaires about lifestyle and psychosocial factors were sent to 5000 respondents aged 20–79 years who answered the first questionnaire, 2500 reporting pain and 2500 with no pain. The profile of these 5000 respondents was consistent with the Japanese demographic composition for sex and age in 2007.[10] A total of 2480 workers aged 20–59 years responded to the second questionnaire and 716 workers who had acute or subacute pain were excluded from our analyses. Thus, we included the data on 1764 workers aged 20–59 years, 532 with chronic pain and 1232 with no pain, in the analyses.

The proportions for the different job categories were 29.5% specialists, 8.6% managers, 28.2% white-collar workers, 8.4% sales workers, 3.3% service workers, 0.6% primary sector workers, 2.2% transportation or communication workers, 6.0% menial labourers, and 13.2% others. The majority, 86.2%, were full time while 13.8% were part time.

Ethics

All participants had given their informed consent before responding to the questionnaire. A credit point for internet shopping was given as an incentive to the respondents.

Measures

Job satisfaction and social support from supervisors and co-workers were measured using subscales of the Brief Job Stress Questionnaire.[12] The questionnaire section on social support from supervisors and co-workers consisted of three items ('How well do you get along with your supervisors/co-workers?, 'When you experience difficulties, how much do you rely on your supervisors/co-workers?' and 'How often do you consult your supervisors/co-workers about your private issues/problems?'). Each item was rated on a four-point scale ranging from 1 (sufficient) to 4 (poor), and the total score was calculated by summing the three items for a total score ranging from 3 to 12 points (with lower scores indicating greater levels of support). Subsequently, we calculated the quartiles of scores for social support from supervisors and from co-workers (higher quartile indicating greater level of support) and classified supervisor support as low (Q1, 12–10), intermediate (Q2, 9; Q3, 8–7) or high (Q4, 6–3 points), and co-worker support as low (Q1, 12–9), intermediate (Q2, 8; Q3, 7–6) or high (Q4, 5–3). Job satisfaction was classified into four categories: dissatisfied, somewhat dissatisfied, relatively satisfied or satisfied.

The primary outcome measure was chronic pain prevalence in the entire cohort. The participants also answered questions related to their own pain such as the pain sites, pain intensity at each site, the site of dominant pain, the duration of dominant pain and disability due to dominant pain. Pain intensities were scored on an 11-point Numerical Rating Scale (NRS) (0=no pain, 10=worst pain imaginable). A score ≥5 for the dominant pain site during the past 3 months was defined as chronic pain.

The secondary outcome was the prevalence of low Euro QoL (EQ-5D), defined as below the mean of 0.76 of the present study, in workers with chronic pain according to the NRS. We used the Japanese version of the EQ-5D instrument to measure HRQoL.[13] The EQ-5D includes five dimensions: mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. Each dimension is divided into three degrees of severity: 1 (no problem), 2 (moderate) and 3 (extreme problems). The five numbers expressing severity on the five dimensions (eg, 11 233, 22 112 or 11 333) are arranged in the order above, generating 3^5 (or 243) different health statuses. The 243 health statuses are then converted into a single index score called the 'utility value' from 0 (dead) to 1 (full health) according to the conversion table for the Japanese EQ-5D.[13]

The presence of severe depressive symptoms was treated as a confounding factor and used as an adjustment variable because depression is strongly associated with psychosocial factors, chronic pain and quality of

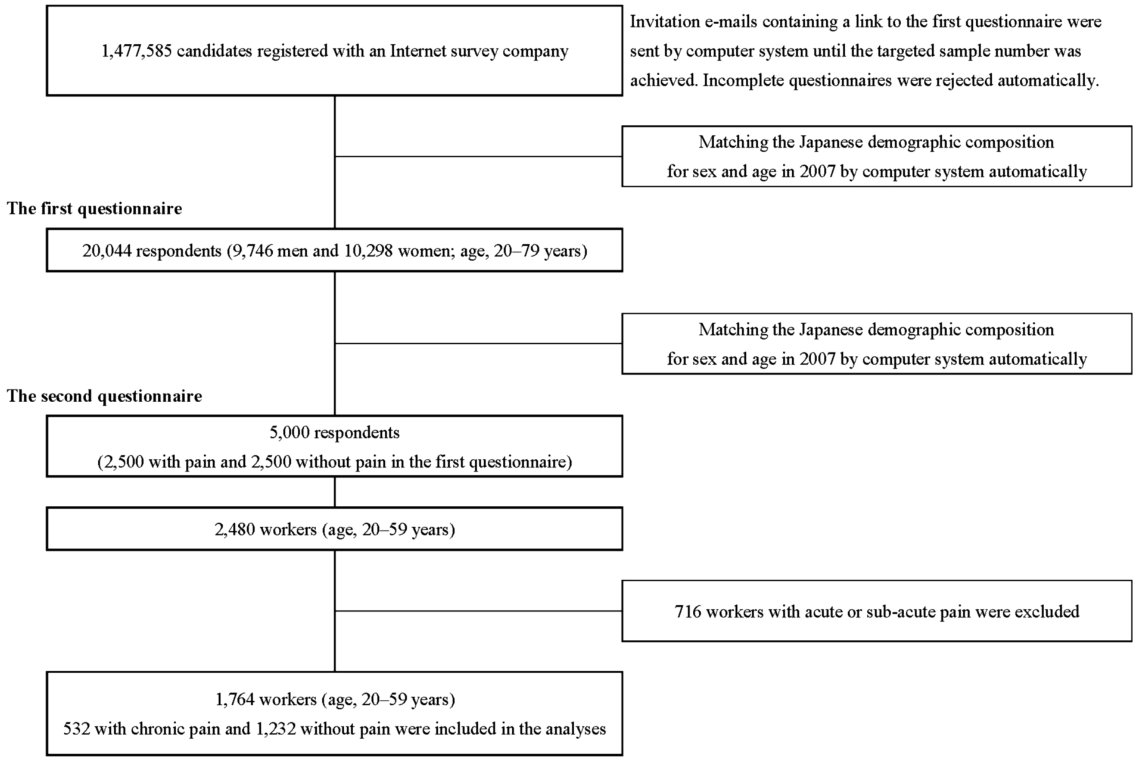

Figure 1 Flow chart of the sampling procedure ending in the sample being analysed in the current study.

life.[14] In the present study, the presence of severe depressive symptoms was defined as a Mental Health Inventory (MHI-5) score <52.[15] The MHI-5 is equal to the 36-item Short Form Health Survey (SF-36) 'mental health' domain.[16] The MHI-5 contains the following five questions: 'How much of the time during the last month have you: (1) been a very nervous person, (2) felt downhearted and blue, (3) felt calm and peaceful, (4) felt so down in the dumps that nothing could cheer you up and (5) been a happy person?' The respondents choose a number from 1 (all of the time) to 6 (none of the time). The score on the MHI-5, ranging from 5 to 30 points, is converted to a 100-point scale.[15] A previous Japanese study confirmed that the cut point of <52 on the MHI-5 (corresponding to ≥56 on the 20-item Zung Self-rating Depression Scale, ZSDS) was useful for screening severe depressive symptoms, with sensitivity of 91.8% and specificity of 84.6%.[15]

Statistical analysis

Analysis of covariance was used to test for differences in age-adjusted means and proportions of the various clinicodemographic characteristics recorded for the analysis. We analysed the association between work-related psychosocial factors and the prevalence of chronic pain among all workers, and the prevalence of low EQ-5D (<the mean of 0.76) among workers with chronic pain.

Multivariable-adjusted ORs and 95% CIs were calculated using the logistic regression model. The adjustment variables included age, sex, smoking status (never-smoker, ex-smoker or current smoker), exercise habit (exercise longer than 30 min more than twice a week; yes or no), sleeping time (hours/day), working hours (<40, 40 to 49, 50 to 59, 60 to 69 or >70 h/week), body mass index (kg/m^2, categorised in quintiles), personal consumption expenditure (JPY/month) and presence of severe depressive symptoms (MHI-5<53). When we analysed the association between work-related psychosocial factors and the EQ-5D of workers with chronic pain, we further adjusted for pain intensity as expressed on an 11-point NRS (0=no pain, 10=worst pain imaginable). We could not analyse the data according to job category because the numbers in each were small.

p Values of <0.05 for two-tailed tests were considered statistically significant. All statistical analyses were performed using SAS V.9.4 (SAS Institute Inc, Cary, North Carolina, USA).

RESULTS

We identified 532 workers aged 20–59 years (309 men and 223 women) who had chronic pain, and 1232 workers (783 men and 449 women) without pain. A total of 306 workers with chronic pain (57.5%) reported a severity of 5 points or more on the 11-point NRS for low back pain or neck pain. The prevalence of chronic pain in female workers was significantly higher than in male workers (24.5% vs 19.7%, p<0.05). The prevalence of severe depressive symptoms in patients with chronic pain was 35.3% for men and 37.2% for women, about two-times higher than in pain-free workers (18.1% for men and 21.4% for women).

Table 1 shows the age-adjusted means and proportions of clinicodemographic characteristics according to work-related psychosocial factor category (support from supervisors, support from co-workers, job satisfaction). Workers who received poor support from supervisors and/or co-workers (Q1) and were dissatisfied with their jobs demonstrated a higher prevalence of severe depressive symptoms. A greater proportion of male workers who were dissatisfied with their job exhibited short sleep compared to those with good work-related psychosocial factors. Male workers receiving poor support from supervisors and/or co-workers, and who were dissatisfied with their jobs, exhibited a higher prevalence of chronic pain compared with those satisfied with their jobs and receiving sufficient support. Pain intensity of patients with chronic pain did not vary according to work-related psychosocial factor category.

Table 2 shows the age-adjusted and multivariable ORs of chronic pain patient characteristics according to work-related psychosocial factor category. Male workers with poor job satisfaction exhibited a higher prevalence of chronic pain, and the association remained statistically significant after adjustment for confounding factors and the presence of severe depressive symptoms. The degree of social support from supervisors/co-workers was associated with a progressive decrease in the prevalence of chronic pain among male workers. However, after adjustment for confounding variables and presence of severe depressive symptoms, most of these individual associations between chronic pain prevalence and support quartile were no longer statistically significant. No such associations were found for female workers.

Table 3 shows the age-adjusted and multivariable ORs for low EQ-5D (less than the mean of 0.76) in workers with chronic pain. The mean EQ-5D value of all workers was 0.90 (SD 0.14), 0.96 for those without chronic pain (SD 0.09) and 0.76 (SD 0.12) for those with chronic pain; therefore, 0.76 was used as the cut-off point. Work-related social factors were significantly associated with the low EQ-5D (less than the mean of 0.76) among workers of both sexes with chronic pain in the age-adjusted model and model 1. However, those associations were no longer statistically significant in the severe depressive syndrome-adjusted model (model 2), except for the category, support from supervisors/co-workers for female workers. In the entire cohort of patients with chronic pain (men and women), there was a significantly higher prevalence of low EQ-5D in those reporting poor support from supervisors and from those reporting poor support from co-workers. These associations were statistically significant in neither men nor women separately.

DISCUSSION

These results reveal a significant association between job dissatisfaction and the prevalence of chronic pain in Japanese male workers, in accord with previous findings of a link between job dissatisfaction and chronic musculoskeletal pain among European and North American workers.[2 5 6] However, no gender differences were found in those studies, while the link between job dissatisfaction and chronic pain was specific to men in the current study.

In general, there are gender differences in pain and analgaesia,[17 18] so we stratified participants by sex. Previous studies have found that women experience chronic pain more often than men.[17 18] Similarly, the prevalence of chronic pain was significantly higher in women than in men in the current study. However, job satisfaction was associated with the prevalence of chronic pain only among men. It was suggested that the incidence of chronic pain may be more influenced by job satisfaction among men than among women in Japan. Men generally work longer hours than do women in Japan, with an average daily working time of 416 min for men and 290 min for women in 2011.[19] On the other hand, many Japanese men do not share housework, averaging only 42 min daily compared with 215 min for women.[19] In our study, the proportion of male workers who had been working >60 h per week (15.5%) were more than that of female workers (4.2%).Thus, women may be more strongly affected by psychosocial factors at home than at work due to shorter working hours or cultural expectations. However, psychosocial factors in private life were not examined in this study, so we could not investigate the reasons for this gender difference in the impact of psychosocial factors on chronic pain.

Several recent studies have recommended that patients with chronic pain should continue to work and not take prolonged leave;[2–4] however, the success of this vocational rehabilitation model could depend on a favourable work environment. Indeed, support from supervisors and co-workers did have a positive effect on workers with chronic pain according to self-reported HRQoL. Similarly, supportive relationships at work led to better HRQoL of employees with severe mental illness.[4] This need for supportive supervisors and co-workers may result from a lower resiliency and capacity to cope with stress compared with healthy workers.[20]

We investigated the prevalence of low EQ-5D (defined as below the mean of 0.76) among workers with chronic pain as the secondary outcome of our research. In a Finnish study, the mean EQ-5D of the general population was 0.84 and that of the subpopulation with back pain was 0.74.[21] This is similar to the mean EQ-5D of Japanese workers in the current study, most of whom suffered from back or neck pain. Thus, EQ-5D appears to reflect impaired QoL resulting from chronic musculoskeletal pain. The EQ-5D can also detect meaningful changes in other clinical conditions.[22] For instance,

Table 1 Age-adjusted mean values and proportions of characteristics according to the categories of work-related psychosocial factors among workers aged 20–59 years

	Support from supervisors				Support from co-workers				Job satisfaction			
The quartiles of scores for social support	**Q4**	**Q3**	**Q2**	**Q1**	**Q4**	**Q3**	**Q2**	**Q1**				
Score; with lower scores indicating greater levels of support	**6–3 points**	**8–7 points**	**9 points**	**12–10 points**	**5–3 points**	**7–6 points**	**8 points**	**12–9 points**	**Satisfied**	**Relatively satisfied**	**Somewhat dissatisfied**	**Dissatisfied**
Men, n=1092												
n	285	332	232	243	200	351	226	315	136	638	234	84
Age (years)	40.0 (0.6)	42.7 (0.5)	40.3 (0.7)	41.2 (0.6)	40.6 (0.6)	43.0 (0.7)	41.4 (0.5)	39.6 (0.7)	39.6 (0.9)	41.6 (0.4)	41.1 (0.7)	40.4 (1.1)
Current smoker (%)	32.2	37.3	28.4	32.5	37.0	31.6	32.3	32.7	31.6	31.3	36.8	38.1
Have an exercise habit (%)	32.3	26.2	27.2	27.6	29	29.3	27	27.6	37.5	28.2	23.9	26.2
Short sleep (%)	6.0	2.7	3.0	8.2	3.5	5.1	3.5	6.3	3.7	4.4	3.8	13.1†
Overwork (%)	14.7	12.3	14.7	20.6	13.0	13.7	19.0	15.9	11.8	14.4	19.7*	15.5
Body mass index ≥25 (%)	25.6	26.2	26.7	25.9	23.5	24.2	29.2	27.6	22.8	27.0	26.5	23.8
Personal consumption expenditure (×10 000 JPY/month)	29.1	32.2	28.7	27.6	26.3	34.7*	28.6	26.7	32.8	28.8	28.9	32.6
Severe depressive symptoms (%)	13.7	17.2	23.3†	41.6‡	11.5	14.8	19.5*	41.9‡	8.8	13.5	38.5‡	75.0‡
Chronic pain (%; number of participants with chronic pain, n=309)	23.5 (67)	25.9 (86)	30.6 (71)	35.0† (85)	25.0 (50)	21.4 (75)	30.1 (69)	36.5† (115)	19.9 (27)	25.7 (164)	32.1* (75)	51.2‡ (43)
Intensity of pain of participants with chronic pain (Numerical Rating Scale)	7.0	7.0	6.9	6.9	7.2	7.0	7.0	6.8	6.4	7.1*	6.9	7.0
Women, n=672												
n	160	210	110	192	149	215	95	213	74	411	134	53
Age (years)	38.9 (0.7)	38.4 (0.9)	40.1 (0.7)	40.2 (0.8)	38.7 (0.7)	40.3 (1.0)	39.6 (0.7)	40.0 (0.8)	40.3 (1.2)	39.8 (0.5)	38.9 (0.9)	37.2 (1.4)
Current smoker (%)	19.4	21.9	21.8	17.7	22.1	22.8	18.9	16.4	20.3	19.2	20.9	24.5
Have an exercise habit (%)	26.9	19.5	18.2	18.8	19.5	22.3	25.3	18.3	27.0	23.6	11.9	13.2
Short sleep (%)	4.4	4.3	1.8	6.3	3.3	4.2	7.4	4.2	1.4	4.1	7.5*	3.8

Continued

Table 1 Continued

The quartiles of scores for social support	Support from supervisors				Support from co-workers				Job satisfaction			
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1				
Score; with lower scores indicating greater levels of support	6–3 points	8–7 points	9 points	12–10 points	5–3 points	7–6 points	8 points	12–9 points	Satisfied	Relatively satisfied	Somewhat dissatisfied	Dissatisfied
Overwork (%)	5.6	5.2	1.8	3.1	5.4	4.7	2.1	3.8	6.8	4.4	3.7	0
Body mass index ≥25 (%)	13.1	13.3	15.5	14.1	12.8	15.8	10.5	14.1	9.5	14.8	17.2	3.8
Personal consumption expenditure (×10 000 JPY/month)	25.6	27.3	29.5	24.6	24.3	27.3	26.2	27.3	24.2	25.8	30.1	26.3
Severe depressive symptoms (%)	10.6	23.3†	27.3†	43.2‡	12.1	23.3*	25.3*	40.8‡	10.8	16.1	46.3‡	81.1‡
Chronic pain (%; number of participants with chronic pain, n=223)	30.0 (48)	31.4 (66)	37.2 (41)	35.4 (68)	33.6 (50)	31.6 (68)	26.3 (25)	37.6 (80)	29.7 (22)	29.2 (120)	44.0* (59)	41.5 (22)
Intensity of pain of participants with chronic pain (Numerical Rating Scale)	7.5	6.9	7.4	7.8	7.5	7.2	6.8*	7.6	7.4	7.2	7.7	7.5

Test for significance from the category of Q4, or satisfied.
In parentheses: SEs.
The quartiles of scores for social support from supervisors and from co-workers were calculated, and classified as low (Q1), intermediate (Q2; Q3) or high (Q4).
*p<0.05, †<0.01, ‡<0.001.

Table 2 ORs (ORs, 95% CI) of chronic pain according to the categories of work-related psychosocial factors among workers aged 20–59 years

The quartiles of scores for social support Score; with lower scores indicating greater levels of support	Support from supervisors Q4 6–3 points	Q3 8–7 points	Q2 9 points	Q1 12–10 points	Support from co-workers Q4 5–3 points	Q3 7–6 points	Q2 8 points	Q1 12–9 points	Job satisfaction Satisfied	Relatively satisfied	Somewhat dissatisfied	Dissatisfied
Men, n=1092												
Number of participants	285	332	232	243	200	351	226	315	136	638	234	84
Number of participants with chronic pain	67	86	71	85	50	75	69	115	27	164	75	43
Age-adjusted OR (95% CI)	1.00	1.14 (0.79 to 1.65)	1.44 (0.97 to 2.13)	1.75 (1.20 to 2.56)†	1.00	0.82 (0.54 to 1.23)	1.32 (0.86 to 2.03)	1.73 (1.16 to 2.56)†	1.00	1.40 (0.88 to 2.21)	1.91 (1.15 to 3.15)*	4.23 (2.32 to 7.72)‡
Model 1 OR (95% CI)	1.00	1.22 (0.84 to 1.78)	1.47 (0.98 to 2.19)	1.81 (1.23 to 2.68)†	1.00	0.88 (0.58 to 1.34)	1.35 (0.87 to 2.10)	1.81 (1.21 to 2.72)†	1.00	1.39 (0.87 to 2.22)	1.87 (1.12 to 3.14)*	4.35 (2.35 to 8.04)‡
Model 2 OR (95% CI)	1.00	1.18 (0.81 to 1.73	1.35 (0.90 to 2.03)	1.42 (0.95 to 2.13)	1.00	0.85 (0.56 to 1.30)	1.25 (0.80 to 1.95)	1.40 (0.92 to 2.13)	1.00	1.35 (0.84 to 2.16)	1.51 (0.89 to 2.57)	2.76 (1.43 to 5.31)‡
Women, n=672												
Number of participants	160	210	110	192	149	215	95	213	74	41	134	53
Number of participants with chronic pain	48	66	41	68	50	68	25	80	22	120	59	22
Age-adjusted OR (95% CI)	1.00	1.07 (0.68 to 1.67)	1.36 (0.81 to 2.27)	1.26 (0.80 to 1.98)	1.00	0.91 (0.58 to 1.42)	0.71 (0.40 to 1.25)	1.17 (0.76 to 1.82)	1.00	0.97 (0.56 to 1.67)	1.84 (1.00 to 3.36)*	1.62 (0.77 to 3.41)
Model 1 OR (95% CI)	1.00	1.03 (0.65 to 1.64)	1.45 (0.85 to 2.48)	1.31 (0.81 to 2.10)	1.00	0.95 (0.60 to 1.51)	0.78 (0.43 to 1.40)	1.28 (0.81 to 2.03)	1.00	1.03 (0.58 to 1.82)	1.66 (0.87 to 3.17)	1.98 (0.90 to 4.36)
Model 2 OR (95% CI)	1.00	0.95 (0.59 to 1.52)	1.29 (0.75 to 2.24)	1.05 (0.64 to 1.71)	1.00	0.86 (0.54 to 1.38)	0.69 (0.38 to 1.26)	1.04 (0.65 to 1.68)	1.00	0.98 (0.55 to 1.74)	1.31 (0.67 to 2.56)	1.23 (0.53 to 2.86)
Total, n=1764												
Number of participants	445	542	342	435	349	566	321	528	210	1049	368	137
Number of participants with chronic pain	115	152	112	153	100	143	94	195	49	284	134	65
Age-adjusted OR (95% CI)	1.00	1.12 (0.84 to 1.49)	1.41 (1.03 to 1.92)*	1.53 (1.15 to 2.05)†	1.00	0.85 (0.63 to 1.15)	1.07 (0.77 to 1.50)	1.47 (1.10 to 1.97)*	1.00	1.21 (0.86 to 1.72)	1.88 (1.28 to 2.77)†	2.94 (1.85 to 4.68)‡
Model 1 OR (95% CI)	1.00	1.15 (0.86 to 1.53)	1.44 (1.05 to 1.98)*	1.58 (1.17 to 2.12)†	1.00	0.90 (0.66 to 1.22)	1.01 (0.78 to 1.56)	1.55 (1.15 to 2.09)†	1.00	1.20 (0.84 to 1.72)	1.76 (1.18 to 2.62)†	3.13 (1.94 to 5.06)‡
Model 2 OR (95% CI)	1.00	1.08 (0.81 to 1.45)	1.31 (0.95 to 1.81)	1.25 (0.91 to 1.70)	1.00	0.84 (0.62 to 1.15)	1.01 (0.71 to 1.43)	1.22 (0.89 to 1.67)	1.00	1.15 (0.80 to 1.65)	1.42 (0.94 to 2.13)†	1.99 (1.19 to 3.32)†

Model 1: adjusted for age, sex, smoking, exercise habit, sleep time, working time, body mass index and personal consumption expenditure.
Model 2: adjusted for the aforementioned variables plus existence of severe depressive symptoms.
The quartiles of scores for social support from supervisors and from co-workers were calculated, and classified as low (Q1), intermediate (Q2; Q3) or high (Q4).
Test for significance from the category of Q4 or satisfied.
*p<0.05, †p<0.01, ‡p<0.001.

Table 3 ORs (ORs, 95%CI) of below Euro QoL (EQ-5D) mean value according to the categories of work-related psychosocial factors among workers aged 20–59 years

The quartiles of scores for social support Score; with lower scores indicating greater levels of support	Support from supervisors				Support from co-workers				Job satisfaction			
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1				
	6–3 points	8–7 points	9 points	12–10 points	5–3 points	7–6 points	8 points	12–9 points	Satisfied	Relatively satisfied	Somewhat dissatisfied	Dissatisfied
Men, n=309												
Number of participants	67	86	71	85	50	75	69	115	27	164	75	43
Number of participants with<EQ-5D mean value	20	24	21	47	12	20	24	56	8	45	29	30
Age-adjusted OR	1.00	0.87 (0.43 to 1.78)	0.99 (0.48 to 2.06)	2.87 (1.46 to 5.65)†	1.00	1.08 (0.47 to 2.50)	1.57 (0.68 to 3.61)	2.91 (1.37 to 6.14)‡	1.00	0.87 (0.35 to 2.13)	1.44 (0.56 to 3.73)	5.56 (1.94 to 15.98)‡
Model 1 OR	1.00	0.81 (0.39 to 1.70)	0.84 (0.39 to 1.82)	2.60 (1.28 to 5.29)†	1.00	1.03 (0.43 to 2.45)	1.45 (0.62 to 3.42)	2.70 (1.24 to 5.90)*	1.00	0.78 (0.31 to 1.96)	1.25 (0.47 to 3.34)	5.09 (1.70 to 15.25)†
Model 2 OR	1.00	0.61 (0.27 to 1.36)	0.66 (0.29 to 1.51)	1.43 (0.65 to 3.12)	1.00	0.87 (0.34 to 2.24)	1.10 (0.44 to 2.75)	1.48 (0.63 to 3.47)	1.00	0.74 (0.28 to 1.99)	0.71 (0.24 to 2.10)	2.09 (0.62 to 7.09)
Women, n=223												
Number of participants	48	66	41	68	50	68	25	80	22	120	59	22
Number of participants with <EQ-5D mean value	13	25	17	41	14	22	13	47	6	42	32	16
Age-adjusted OR	1.00	1.64 (0.73 to 3.69)	1.90 (0.78 to 4.64)	4.09 (1.84 to 9.10)‡	1.00	1.23 (0.55 to 2.74)	2.78 (1.02 to 7.58)*	3.66 (1.71 to 7.84)‡	1.00	1.44 (0.52 to 3.95)	3.15 (1.08 to 9.19)*	7.24 (1.90 to 27.55)†
Model 1 OR	1.00	1.63 (0.68 to 3.92)	1.71 (0.67 to 4.35)	3.95 (1.69 to 9.22)†	1.00	1.11 (0.47 to 2.60)	2.49 (0.85 to 7.30)*	3.45 (1.55 to 7.66)†	1.00	1.42 (0.46 to 4.38)	3.43 (1.05 to 11.26)*	7.55 (1.77 to 32.20)†
Model 2 OR	1.00	1.19 (0.47 to 3.01)	1.22 (0.45 to 3.32)	2.54 (1.04 to 6.21)*	1.00	0.86 (0.35 to 2.12)	1.60 (0.51 to 5.05)	2.59 (1.12 to 5.97)*	1.00	1.36 (0.42 to 4.38)	2.06 (0.58 to 7.28)	3.49 (0.74 to 16.36)
Total, n=532												
Number of participants	115	152	112	153	100	143	94	195	49	284	134	65
Number of participants with <EQ-5D mean value	33	49	38	88	26	42	37	103	14	87	61	46

Continued

Table 3 Continued

The quartiles of scores for social support Score; with lower scores indicating greater levels of support	Support from supervisors				Support from co-workers				Job satisfaction			
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1				
	6–3 points	8–7 points	9 points	12–10 points	5–3 points	7–6 points	8 points	12–9 points	Satisfied	Relatively satisfied	Somewhat dissatisfied	Dissatisfied
Age-adjusted OR	1.00	1.16 (0.68 to 1.98)	1.30 (0.74 to 2.29)	3.35 (2.00 to 5.61)‡	1.00	1.19 (0.67 to 2.11)	2.01 (1.08 to 3.74)*	3.32 (1.95 to 5.67)‡	1.00	1.11 (0.56 to 2.17)	2.07 (1.02 to 4.22)*	6.57 (2.88 to 15.03)‡
Model 1 OR	1.00	1.07 (0.62 to 1.85)	1.15 (0.65 to 2.06)	3.03 (1.78 to 5.15)‡	1.00	1.12 (0.62 to 2.02)	1.82 (0.97 to 3.44)	3.18 (1.84 to 5.50)‡	1.00	1.06 (0.53 to 2.15)	1.94 (0.92 to 4.09)	6.42 (2.72 to 15.19)‡
Model 2 OR	1.00	0.82 (0.46 to 1.48)	0.89 (0.48 to 1.66)	1.85 (1.04 to 3.28)*	1.00	0.92 (0.49 to 1.74)	1.38 (0.70 to 2.73)	2.07 (1.15 to 3.70)*	1.00	1.02 (0.49 to 2.11)	1.14 (0.52 to 2.52)	2.77 (1.09 to 7.01)*

Model 1: adjusted for age, sex, smoking, exercise habit, sleep time, working time, body mass index, personal consumption expenditure, intensity of pain.
Model 2: adjusted for aforementioned variables plus existence of severe depressive symptoms.
The quartiles of scores for social support from supervisors and from co-workers were calculated, and classified as low (Q1), intermediate (Q2; Q3) or high (Q4).
Test for significance from the category of Q4 or satisfied.
*p<0.05, †p<0.01, ‡p<0.001.

intensity of migraine was correlated with EQ-5D.[23] Patients with chronic pain reporting poor support in the workplace showed a higher prevalence of low mean EQ-5D, indicating that these work-related psychosocial factors are important for maintenance of general health status and functional well-being.

Absence from work because of sickness for regional pain symptoms is much less common in Japan compared with that in the UK.[24] Compared with the UK, the reported rates of sick leave for regional pain symptoms in Japan are less than one-third (only 5%).[24 25] According to the population-based survey,[26] the prevalence of chronic pain in Japan (22.9%) is similar to that in Europe;[2] therefore, the number of people who are working with chronic pain without absence from work may be larger in Japan than in the UK. This cultural difference may reflect the result of a wide range HRQoL of workers with chronic pain being observed in the present study; thus, the association between work-related psychosocial factors and EQ-5D among workers with chronic pain may be detected sensitively in the current Japanese study.

Depression is strongly associated with psychosocial factors, chronic pain and QoL in the clinical setting.[14] The lifetime prevalence of major depression in primary care settings is 5–10%,[27] and the reported prevalence of pain in patients with depression averages about 65% (range 15–100%).[28] The estimated coexistence of major depression with chronic pain in the general population is 18% (4.7–22%).[28] In fact, the presence of severe depressive symptoms was the most powerful confounder in our study.

Limitations

There are several limitations to our study. First, the participants may not be truly representative of the general population. Although the demographic profile of respondents was consistent with the Japanese demographic composition for sex and age in 2007, the 1764 participants who answered the detailed questionnaire were selected purposefully (by eliminating those with acute and subacute pain). According to the Annual Report on the Labor Force Survey in 2009,[29] the percentage of the Japanese labour force aged 20–59 years was 92.5% for men and 69.9% for women, while 88.5% of male respondents and 52.2% of female respondents were currently in the labour force. The proportions of job categories were biased. Specialists and white-collar workers have a majority (57.7%), and the proportion of primary sector workers was very low (0.6%). Moreover, factors influencing the decision to respond to the web-based survey may have biased the distribution. For example, it may have selected against extremely busy workers or older workers less familiar with the internet. In addition, the respondents may have been particularly interested in pain research, possible due to personal affliction. The sampling issues of the web-based survey were noted before.[30] This difference, particularly the low portion of female respondents in the workforce, could have influenced the results.

Second, our questionnaire included only three psychosocial factors, social support from supervisors, support from co-workers and job satisfaction. 'Job demand' and 'job control'[31] have also been included as work-related psychosocial factors, but these were not examined in this study. Our questionnaire did not include social support in private life. Furthermore, individual psychosocial factors such as 'fear avoidance', 'pain catastrophising' and 'resilience' were not investigated in the present study.

Third, patients with severe chronic pain who took sick leave or had retired due to pain were not included in our study. This limitation could reduce the statistical power to examine the association between work-related psychosocial factors and chronic pain.

CONCLUSION

Male workers reporting job dissatisfaction had a higher prevalence of chronic pain than those reporting job satisfaction. Among workers with chronic pain, those reporting poor social support and job dissatisfaction had a greater frequency of low HRQoL. Thus, work-related psychosocial factors are critical influences on the HRQoL of workers with chronic pain.

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Contributors KY conceived the original idea for the study, performed the analyses of the data and drafted the manuscript. KM and HI revised the manuscript, contributed to the interpretation of the data and added critical comments. HI and AK revised the manuscript and contributed with comments. All the authors approved the final version.

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Original Article

Effect of pelvic forward tilt on low back compressive and shear forces during a manual lifting task

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Abstract. [Purpose] To examine the effect of an instruction to increase pelvic forward tilt on low back load during a manual lifting task in the squat and stoop postures. [Subjects] Ten healthy males who provided informed consent were the subjects. [Methods] Kinetic and kinematic data were captured using a 3-dimensional motion analysis system and force plates. Low back compressive and shear forces were chosen as indicators of low back load. The subjects lifted an object that weighed 11.3 kg, under the following 4 conditions: squat posture, stoop posture, and these lifting postures along with an instruction to increase pelvic forward tilt. [Results] In the squat posture, the instruction to increase pelvic forward tilt reduced the low back compression and shear forces. [Conclusion] The present results suggest that a manual lifting task in the squat posture in combination with an instruction to increase pelvic forward tilt can decrease low back compression and shear forces, and therefore, might be an effective preventive method for low back pain in work settings.
Key words: Manual lifting task, Low back load, Motion analysis

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INTRODUCTION

A large number of people in developed countries have low back pain. The prevalence rate of lifetime low back pain in Japan was reported to be 83.5%[1)], and low back pain accompanies most occupational diseases. Manual lifting tasks are reported to confer the highest risk of low back pain in occupational work[2, 3)]. Lifting tasks are often conducted with 2 types of posture, namely the squat posture, with the knees and hips flexed and the back extended, and the stoop posture, with the hips and back flexed and the knees extended. Previous studies have compared low back load between these 2 conditions. The squat technique is widely recommended to prevent low back pain while conducting lifting tasks. However, Van Dieën et al.[4)] reported in a systematic review that no difference in low back load was observed between manual lifting tasks with the squat posture and those with the stoop posture. A large trunk forward bending angle is needed in combination with increase of pelvic forward tilt in the stoop posture. Less trunk forward bending angle in the squat posture than in the stoop posture, but the pelvic forward tilt angle decreases. Therefore, the appropriate posture for minimizing low back load in lifting tasks is still unclear. Low back load during a lifting task is biomechanically and directly affected by the lever arm, which is the distance from the center of the rotation of the low back joint to the center of gravity of the object. Accordingly, increasing pelvic forward tilt while executing the lifting task would decrease the lever arm, and thus, it might decrease low back load

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during the lifting task. However, no previous study has compared low back load between with and without increase of pelvic forward tilt during the lifting task. Hence, the purpose of this study was to examine the effect of an instruction to increase pelvic forward while lifting an object with the squat and stoop postures on low back load.

SUBJECTS AND METHODS

The participants were 10 healthy male university students (mean ± SD: age, 20.9 ± 0.5 years; height, 174.9 ± 4.3 cm; weight, 64.1 ± 4.8 kg). The ethics committee of International University of Health and Welfare approved all study procedures (No. 12-210), which were consistent with the Declaration of Helsinki. The authors obtained informed consent from all the subjects prior to their participation in the study.

The experimental tasks were 3 trials of lifting an object from force plates under the following 4 conditions: 1) squat, hips and knees flexed and the back extended; 2) stoop, hips and back flexed and the knees extended; 3) squat and 4) stoop, respectively with an instruction to increase pelvic forward tilt. To increase pelvic forward tilt, participants were instructed to move their navel closer. After practicing each lifting posture with the instruction to increase pelvic forward tilt several times, subjects conducted the lifting tasks. In a pilot study, the subjects who performed squat and stoop lifting without an instruction to increase pelvic forward tilt changed their lifting maneuvers after conducting the lifting with the instruction. Therefore, the subjects first lifted the object with squat and stoop without any instruction in a random order, and then they lifted the object with squat and stoop with the instruction to increase pelvic forward tilt in a random order. Subjects lifted a box (37.5 × 50 × 21 cm; 11.3 kg) to waist height. A 10-kg weight was placed in the middle on the bottom of the box that weighed 1.3 kg. Previous studies have reported that the distance from the feet of subjects to an object affects the lifting posture and low back load[5, 6]. Hence, in this study, the object was placed on the centerline of 2 force plates, at one half the length of the foot from the toe, as in a previous study[7]. In addition, experiments were conducted after repeatedly practicing each task, and the subjects had enough time to rest, at least 5 minutes, between tasks (Fig. 1).

A 3-dimensional motion analysis system consisting of 10 infrared cameras (Vicon MX, Vicon, Oxford, UK) and 4 force plates (AMTI, Watertown, MA, USA) was used to record 3-dimensional marker displacements and ground reaction force data at a sampling frequency of 100 Hz. Forty-five reflective markers were attached to each subject according to the procedure described in the study of Katsuhira et al[7]. In addition, 4 markers were also attached to the upper frame of the box.

Several studies have used electromyography (EMG) to evaluate low back load during lifting tasks[8, 9]. Several studies have also used 3D motion analysis systems to measure low back compression force and low back shear force as parameters of low back load. The analysis of low back compression force has the advantage, that it can be compared with the safe limit proposed by National Institute of Occupational Safety and Health (NIOSH)[10]. Low back compressive and shear forces were chosen as indicators of low back load in the present study. The computation methods reported by Yamazaki et al.[11] and Katsuhira et al.[7] were used to obtain these forces in our study. Katsuhira et al. reported that low back compressive and shear forces almost simultaneously show peak values[7]. Therefore, they extracted the shear force at the time of the peak of the low back compressive force. As the same tendency was confirmed in our pilot study, the shear force was calculated at the time of the peak of the low back compressive force, and the pelvic angle and lever arm from the L4/5 joint to the center of the gravity of were calculated at the same time. Low back compressive and shear forces were normalized using the subjects'

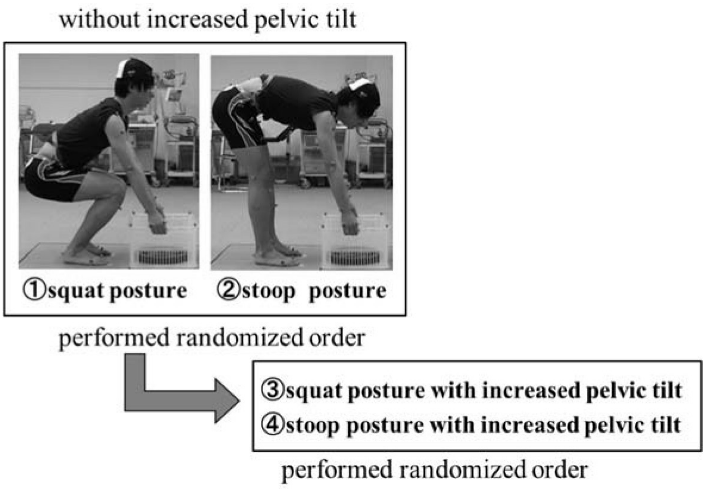

Fig. 1. Experimental condition

body masses to offset the difference in physical attributes between the subjects, in accordance with the method described in a previous study[7]. Moreover, the actual values of the low back compressive and shear forces before the normalization using body mass were compared with the safe limits of the compressive force reported by the NIOSH[10], and the shear force reported by Gallagher et al[12].

The paired t-test was used to assess individual differences between with and without the instruction to increase pelvic forward tilt in each posture. In addition, repeated-measures analysis of variance (ANOVA) was used to compare the differences among the 4 experimental conditions, and the Bonferroni post hoc test was conducted to identify which lifting condition showed the minimum value of low back load. P values < 0.05 were considered statistically significant. Statistical analysis was conducted by using the software package SPSS version 20 (IBM Inc., Armonk, NY, USA).

RESULTS

The mean values of the low back compression and shear forces are shown in Table 1. In the comparison between conditions with and without the instruction to increase pelvic forward tilt, the paired t-test showed there was a significant decrease in low back compression force in the squat posture with the instruction to increase pelvic forward tilt, but not in the stoop posture. In addition, one-way repeated-measures ANOVA and the post hoc test showed there was a significant increase in the low back compressive force in the squat posture without the instruction to pelvic forward tilt, compared the other 3 conditions. The mean increase peak values of the low back compression force in the present study were compared with the safety limit recommended by NIOSH, which is 3400 N. Low back compression force exceeded the safe limit under all 4 conditions.

The paired t-test showed there were no significant differences in standardized low back shear force in both the squat and stoop postures between with and without the instruction to pelvic forward tilt. Moreover, the one-way repeated-measures ANOVA and post hoc test showed there was a significantly smaller value of the low back shear force in the squat posture with the instruction to increase pelvic forward tilt than in the other 3 conditions.

In the comparison of the present results of low back shear force to the safe limit of the shear force reported by Gallagher et al., low back shear forces under all 4 conditions were lower than the safe limit.

The mean pelvic forward tilt angle and distance from the low back joint to the center of gravity of the object are shown in Table 2. The paired t-test showed there was a significant increase in pelvic forward tilt in the squat posture when subjects were instructed to increase pelvic forward tilt, but not in the stoop posture. Also, there was a significant decrease in the lever arm from the low back joint to the center of gravity of the object in the squat posture with the instruction to increase pelvic forward tilt but not in the stoop posture.

Table 1. Mean values of low back compression and shear forces

	Squat posture		Stoop posture		
	without increased pelvic tilt	with increased pelvic tilt	without increased pelvic tilt	with increased pelvic tilt	ANOVA
Normalized low back compression force (N/kg)	66.0±4.5*	59.5±5.5	59.60±5.1	58.2±4.9	a*, b*,c*
Low back compression force (N)	4,219.3±4.5	3,819.2±485.6	3,820.2±441.1	3,725.5±363.9	a*, b*,c*
Normalized low back shear force (N/kg)	1.5±0.5	1.15±0.6	1.8±0.3	1.8±0.4	a*,c*,d*,e*
Low back shear force (N)	92.7±31.1	75.4±38.7	113.4±20.4	117.1±25.1	a*,b*,c*,d*,e*

Mean ± SD, *p<0.05
a: Squat posture without increased pelvic tilt vs. squat posture with increased pelvic tilt
b: Squat posture without increased pelvic tilt vs. stoop posture without increased pelvic tilt
c: Squat posture without increased pelvic tilt vs. stoop posture with increased pelvic tilt
d: Squat posture with increased pelvic tilt vs. stoop posture without increased pelvic tilt
e: Squat posture with increased pelvic tilt vs. stoop posture with increased pelvic tilt
f: Stoop posture without increased pelvic tilt vs. stoop posture with increased pelvic tilt

Table 2. Mean values of pelvic forward tilt angle and distance from the low back joint to the center of gravity of the object

	Squat posture		Stoop posture	
	without increased pelvic tilt	with increased pelvic tilt	without increased pelvic tilt	with increased pelvic tilt
Pelvis forward tilt angle (°)	17.8±17.2	31.1±23.6*	41.3±12.5	44.2±12.7
Distance from low back joint to Center of gravity of an object (mm)	611.4±50.2*	569.2±45.4	505.3±38.9	487.6±35.7

Mean ± SD, *p<0.05

DISCUSSION

Giving an instruction to increase pelvic forward tilt significantly decreased the low back compression force only during lifting in the squat posture. Accordingly, an instruction to increase pelvic forward tilt might be more beneficial to decrease low back load during lifting in the squat posture than in the stoop posture. Low back compression force is an indicator of low back load which is related to low back joint moment. Low back extension moment especially relates to low back compression force in lifting tasks[7]. The distance from the L4/5 joint to the center of gravity of the object or the center of gravity of the head, trunk and arms is defined as the lever arm of the low back extension moment.

When the instruction to increase pelvic forward tilt was given in the squat position, pelvic forward tilt significantly increased with a significant decrease in the lever arm from the low back joint to the center of gravity of the object. The increase in pelvic forward tilt moved the L4/5 joint forward resulting in a decrease in the lever arm, and thus decreased the low back compressive force during lifting in the squat posture. However, no significant differences in the pelvic forward tilt or lever arm were found between with and without the instruction to increase pelvic forward tilt in the stoop posture. Lifting in the stoop posture is requires increase of pelvic forward tilt. Therefore, further increase in pelvic forward tilt might be difficult to perform.

Normalized low back shear force was the smallest in the squat posture with pelvic tilt. The trunk bending angle in the squat posture was smaller than that in the stoop posture. Low back shear force was calculated as the anteroposterior direction force applied to the L4/5 joint. Thus, a small trunk bending angle could decrease the low back shear force. Moreover, increasing pelvic forward tilt increases lumbar lordosis, which would have contributed to the decrease in the low back shear force.

Normalized low back compressive force during lifting in the squat posture without pelvic tilt was the greatest. No significant differences were observed among the other 3 conditions. Normalized low back shear force was significantly smaller during lifting in the squat posture with pelvic tilt. The low back compressive force exceeded the safe limit of 3400 N proposed by NIOSH[10]. Thus, smaller low back shear force would be advantageous the prevention of the risk of low back pain. The values of the low back shear force under all 4 conditions were lower than the safe limit of 700 N proposed by Gallagher et al[12]. However, a previous study suggested that even a small low back shear force might cause damage, resulting in spondylolysis[13]. Hence, the squat posture with an instruction to increase pelvic forward tilt, which can decrease both low back compressive and shear forces, be the recommended lifting posture.

The present study had several limitations. First, low back load was calculated using inverse kinematics. Hence, smaller low back load values were obtained than the actual values of low back load during co-contraction of both the abdominal and back muscles. The authors intend to construct a hybrid model using electromyography and inverse kinematics to obtain the low back load, taking into account co-contraction, in a future study. Second, the subjects of our study were healthy university students. Accordingly, the authors intend to study workers who engage in lifting tasks to confirm the effects of increasing pelvic forward tilt. The authors also intend to investigate the effects of work environment and mental conditions to clarify factors influencing low back load in lifting tasks.

In this study, the effects of an instruction to promote pelvic tilt on low back load during lifting an object from the ground were examined. Making workers aware of pelvic forward tilt during lifting in the squat posture could decrease both low back compressive and shear forces and might lower the incidence of low back pain. Low back pain caused by lifting in work settings has been a problem in both developing and developed countries. The authors recommend the lifting posture identified in this study and suggest that providing education on lifting posture would benefit workers who engage in lifting.

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RESEARCH ARTICLE

Descriptive Epidemiology of Somatising Tendency: Findings from the CUPID Study

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Abstract

Somatising tendency, defined as a predisposition to worry about common somatic symptoms, is importantly associated with various aspects of health and health-related behaviour, including musculoskeletal pain and associated disability. To explore its epidemiological characteristics, and how it can be specified most efficiently, we analysed data from an international longitudinal study. A baseline questionnaire, which included questions from the Brief Symptom Inventory about seven common symptoms, was completed by 12,072 participants aged 20–59 from 46 occupational groups in 18 countries (response rate 70%). The seven symptoms were all mutually associated (odds ratios for pairwise associations 3.4 to 9.3), and each contributed to a measure of somatising tendency that exhibited an exposure-response relationship both with multi-site pain (prevalence rate ratios up to six), and also with sickness absence for non-musculoskeletal reasons. In most participants, the level of somatising tendency was little changed when reassessed after a mean interval of 14 months (75% having a change of 0 or 1 in their symptom count), although the specific symptoms reported at follow-up often differed from those at baseline. Somatising tendency was more common in women than men, especially at older ages, and varied markedly across the 46 occupational groups studied, with higher rates in South and Central America. It was weakly associated with smoking, but not with level of education. Our study supports the use of questions from the Brief Symptom Inventory as a method for measuring somatising tendency, and suggests that in adults of working age, it is a fairly stable trait.

Introduction

Somatising tendency is a predisposition to be unusually aware of, and to worry about, common somatic symptoms [1]. It can be measured through instruments such as the Somatic Symptom Scale [2], the Modified Somatic Perception Questionnaire [3], and a scale derived from the Brief Symptom Inventory [4], and is associated with various aspects of health and health-related behaviour. These include musculoskeletal pain [5–8], especially at multiple sites [9–15], sickness absence from work [16,17], medical consultation [18] and dissatisfaction with medical care [18]. Moreover, the relationship to pain has been observed in longitudinal as well as cross-sectional studies, indicating that tendency to somatise predicts, and is not simply a consequence of, other aspects of health [4–8,14,19,20].

In view of its potential to explain differences in health and behaviour, it is important to understand better the nature of somatising tendency and its descriptive epidemiology. It would be helpful to establish: i) how it can be assessed most efficiently (avoiding redundant information); ii) whether it should be viewed as a long-term trait or a variable state; iii) how it relates to personal characteristics such as sex, age and level of education; and iv) whether it varies importantly between countries and cultures. To explore these questions, we used data from the Cultural and Psychosocial Influences on Disability (CUPID) study, a large international longitudinal investigation of musculoskeletal pain and its determinants [21].

Methods

The design of the CUPID study and its methods of data collection have been reported in detail elsewhere [21]. In brief, the study sample comprised a total of 12,426 participants aged 20–59 years from 47 occupational groups in 18 countries. The occupational groups fell into three broad categories–nurses (including nursing assistants), office staff who regularly used computers, and other workers (mainly manual employees carrying out repetitive tasks with their hands or arms). Each of the 12,426 participants completed a baseline questionnaire (either by self-administration, or in some occupational groups at interview), representing an overall response rate of approximately 70% among those who were eligible for inclusion [21]. After a mean interval of 14 months (range 3–35 months, 84% within 11–19 months), participants in 45 of the 47 occupational groups (n = 11,992) were asked to complete a shorter follow-up questionnaire, and responses were obtained from 9,305 (78%).

The questionnaires were originally drafted in English, and were then translated into local languages where necessary, accuracy being checked by independent back-translation. Among other things, the baseline questionnaire covered sex; age; age of completing full-time education; smoking habits; experience of pain in the past month at each of ten anatomical sites (low back; neck; and right and left shoulder, elbow, wrist/hand and knee) illustrated by diagrams; duration of sickness absence in the past 12 months because of illness other than a problem with the back, neck, upper limb or knees; and somatising tendency.

Somatising tendency was assessed through questions taken from the Brief Symptom Inventory [4], which asked how distressed or bothered (on a five-point ordinal scale from "not at all" to "extremely") the participant had been during the past seven days by each of: faintness or dizziness, pains in the heart or chest, nausea or upset stomach, trouble getting breath, numbness or tingling in parts of the body, feeling weak in parts of the body, and hot or cold spells. A symptom was deemed to occur if it was at least moderately distressing (i.e. in the highest three of the five levels). The same questions were asked both at baseline and at follow-up.

Statistical analysis was carried out with Stata (StataCorp LP 2012, Stata Statistical Software: Release 12.1, College Station, Texas, USA). Pairwise associations between somatic symptoms at baseline were summarised by odds ratios adjusted for sex and age, as were those between symptoms at baseline and at follow-up.

To explore the clustering of symptoms within individuals, we compared the frequency with which a given number of symptoms was reported with the frequency that would have been expected given the overall prevalence of each symptom, and assuming that their occurrence was mutually independent (for example, that experience of chest pain did not make it more or less likely that an individual would suffer from numbness or tingling). Within each of eight strata defined by combinations of sex and 10-year age band, the expected frequency of each possible combination of symptoms was calculated. These expected frequencies were then summed for combinations representing the same total number of symptoms, and the totals further summed across the eight strata to give the overall number of participants who would be expected to have that number of symptoms.

The relationship of different counts of somatic symptoms to multi-site pain in the past month (defined as pain at $\geq$4 of 10 anatomical sites) was assessed by Poisson regression, with adjustment for sex and age. Possible clustering of the pain outcome by occupational group was taken into account by random intercept, multi-level modelling. Associations were summarised by prevalence rate ratios (PRRs) with 95% confidence intervals (95%CIs) based on robust standard errors. To explore whether somatising tendency could be adequately characterised without asking about all seven symptoms, we repeated the analysis, excluding data on specific symptoms in turn, and compared population attributable fractions (PAFs–defined as the proportions of cases in a population that would be eliminated if all people had the same risk as those in the reference category). Confidence intervals for PAFs were derived by bootstrapping. To check that findings were not specific to associations with multi-site pain, we repeated the analyses with an alternative outcome–absence from work for >5 days in the past year for reasons other than a problem with the back, neck, upper limb or knees.

We used simple descriptive statistics to summarise changes in the occurrence of somatic symptoms from baseline to follow-up, and the prevalence of symptoms by occupational group. To test whether there was greater similarity in the occurrence of symptoms within as compared to between countries, we calculated the intra-class correlation coefficient (ICC) for the mean numbers of symptoms by occupational group.

We also investigated the possibility that some occupational groups might have a different profile of somatic symptoms from others. For each combination of occupational group and symptom, we compared the number of participants in the group who reported the symptom, with the number that would have been expected to report it if, after allowance for sex and age, the frequency of the symptom as a proportion of all symptom reports in the occupational group were the same as that in the full study sample. A ratio of observed to expected greater than one was an indication that the occupational group experienced the symptom more often than would have been expected, given their overall tendency to somatise.

Finally, we used Poisson regression to assess the (mutually adjusted) cross-sectional associations of somatising tendency at baseline (defined as report of ≥3 somatic symptoms) with possible risk factors (sex, age, smoking habits and age finished full-time education). Again random intercept modelling was used to allow for possible clustering by occupational group.

Ethical approval for the study was provided by the relevant research ethics committee or institutional review board in each participating country (S1 Appendix).

Results

In one occupational group (office workers in Colombia), one of the questions about somatic symptoms had been omitted. Complete data on somatic symptoms at baseline were available for 12,072 men and women from the remaining 46 occupational groups (98% of all participants from those groups). Table 1 shows the prevalence of each symptom by sex and age. Among men, the prevalence of all symptoms except numbness or tingling was highest in the youngest age group (20–29 years). Women reported each of the seven symptoms more frequently than men, and particularly nausea or upset stomach, hot or cold spells (especially at older ages), and numbness or tingling (again more at older ages). Moreover, in contrast to men, the only symptoms that were most common at age 20–29 years were faintness or dizziness and nausea or upset stomach. In view of these differences, all subsequent analyses were adjusted for sex and age.

Table 2 summarises the associations between pairs of somatic symptoms at baseline. The strongest associations were for pain in the heart or chest with trouble getting breath (OR 9.3), and feeling weak in parts of the body with numbness or tingling in parts of the body (OR 7.9). However, all symptoms were associated with each other, the lowest odds ratio being 3.4.

Table 3 compares the frequency with which specified numbers of symptoms were reported and the frequency that would have been expected had the occurrence of each symptom been statistically independent. More participants than expected reported no symptoms at all (6,016

Table 1. Baseline prevalence (%) of distressing somatic symptoms in past 7 days by sex and age.

Symptom	Men				Women			
	20–29 years	30–39 years	40–49 years	50–59 years	20–29 years	30–39 years	40–49 years	50–59 years
	(N = 1,056)	(N = 1,379)	(N = 1,170)	(N = 641)	(N = 1,954)	(N = 2,487)	(N = 2,172)	(N = 1,213)
Faintness or dizziness	8.0 (85)	7.2 (99)	6.2 (73)	4.8 (31)	17.3 (339)	15.9 (395)	15.1 (328)	12.0 (146)
Pains in heart or chest	10.1 (107)	7.0 (97)	5.8 (68)	5.8 (37)	9.6 (188)	10.0 (248)	12.4 (269)	10.8 (131)
Nausea or upset stomach	16.3 (172)	12.8 (177)	11.4 (133)	9.7 (62)	27.0 (528)	25.3 (630)	22.9 (497)	18.3 (222)
Trouble getting breath	7.1 (75)	5.7 (79)	5.6 (65)	5.5 (35)	10.1 (197)	10.0 (149)	10.6 (230)	10.2 (124)
Hot or cold spells	16.7 (176)	11.8 (163)	10.8 (126)	9.8 (63)	21.6 (423)	21.5 (535)	26.9 (584)	35.1 (426)
Feeling weak in parts of your body	21.3 (225)	17.3 (238)	18.9 (221)	18.6 (119)	26.7 (522)	30.7 (763)	30.9 (671)	28.3 (343)
Numbness or tingling in parts of your body	14.8 (156)	11.6 (160)	16.0 (187)	14.8 (95)	17.2 (336)	25.0 (621)	30.8 (670)	29.6 (359)

Figures in brackets are the numbers of participants with the relevant symptom

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vs. 3,433). However, there were fewer than expected with 1–3 symptoms. The ratio of observed to expected numbers then increased progressively for report of larger numbers of symptoms, rising from 2.75 for four symptoms to 2000 for all seven symptoms.

Table 3 also shows the associations between the number of somatic symptoms and report of pain at ≥4 of 10 anatomical sites. Relative to no somatic symptoms, PRRs for multisite pain increased progressively from 2.3 (95%CI 2.0–2.7) for one somatic symptom to 5.9 (95%CI 4.8–7.4) for five somatic symptoms, and then remained at a similar level for six and seven symptoms. The right-hand columns of the table give the corresponding population attributable fractions (PAFs) and their 95% CIs. Overall, report of at least one somatic symptom accounted for 59.0% of the cases of multi-site pain in the study sample.

To explore whether information about any of the somatic symptoms was effectively redundant, we repeated the analysis of associations with multi-site pain excluding each of the seven symptoms in turn (Table 4). In each case, the PAF for multi-site pain that was associated with report of at least one of the remaining somatic symptoms was lower than in the analysis that included all somatic symptoms (53.2% to 58.6% vs. 59.0%), indicating that each symptom added to the characterisation of somatising tendency, although an index based on only six of the seven symptoms would still work well.

Table 2. Pairwise associations between specific somatic symptoms at baseline.

Symptom at baseline	Faintness or dizziness	Pains in heart or chest	Nausea or upset stomach	Trouble getting breath	Hot or cold spells	Feeling weak in parts of body
Pains in heart or chest	6.6 (492)					
Nausea or upset stomach	5.8 (802)	4.5 (587)				
Trouble getting breath	5.6 (429)	9.3 (450)	4.4 (547)			
Hot or cold spells	4.0 (706)	3.4 (548)	3.8 (1,050)	4.1 (544)		
Feeling weak in parts of body	5.1 (874)	4.7 (681)	3.9 (1,249)	4.9 (653)	4.9 (1,365)	
Numbness or tingling in parts of body	3.9 (705)	4.4 (607)	3.4 (1,032)	4.7 (587)	3.6 (1,113)	7.9 (1,625)

Associations are summarised by odds ratios adjusted for sex and age, with the number of participants reporting both symptoms in brackets

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Table 3. Observed and expected frequency of multiple somatic symptoms and associations with multi-site pain.

Number of somatic symptoms	Observed number of subjects	Expected number of subjects[a]	Ratio of observed to expected	Association with pain at ≥4 vs. 0 anatomical sites					
				Number with no pain	Number with pain at ≥4 sites	PRR[b]	(95% CI)	PAF[c] (%)	(95% CI)
0	6,016	3,433	1.75	3,125	374	1			
1	2,312	4,546	0.51	779	291	2.3	(2.0–2.7)	8.9	(6.8–11.0)
2	1,551	2,817	0.55	336	342	4.0	(3.3–4.8)	13.7	(11.5–15.8)
3	944	1,020	0.93	149	295	5.0	(4.1–6.1)	12.6	(10.7–14.6)
4	618	224.6	2.75	86	226	5.1	(4.1–6.5)	9.7	(7.6–11.7)
5	326	29.26	11.1	30	164	5.9	(4.8–7.4)	7.3	(5.5–9.1)
6	185	2.058	89.9	14	104	6.0	(4.6–7.7)	4.6	(3.2–6.0)
7	120	0.060	2000	15	78	5.8	(4.6–7.2)	3.4	(2.2–4.7)
≥1	6,056	8,639.18	0.70	1,409	1,500	3.8	(3.2–4.5)	59.0	(53.5–64.5)
≥3	2,193	1,276.23	1.72	294	867	5.6	(4.4–7.0)	37.9	(30.9–44.9)

[a] Expected number given the overall prevalence of each symptom, and assuming no association between the occurrence of one symptom and another after allowance for sex and age (in four 10-year strata)

[b] Prevalence rate ratio adjusted for sex and age (in four 10-year strata)

[c] Population attributable fraction

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To check that these patterns of association were not specific to pain outcomes, we repeated the analyses for Tables 3 and 4, taking as an alternative outcome sickness absence in the past 12 months for non-musculoskeletal reasons. In the analysis that included all seven somatic symptoms, PRRs rose progressively from 1.4 (95%CI 1.1–1.7) for report of one symptom to 3.2 (95%CI 2.4–4.2) for report of seven symptoms, and the PAF for report of at least one somatic symptom was 30.4% (Table 5). The PAFs when single somatic symptoms were disregarded ranged from 27.1% to 30.4% (Table 6).

Complete information about somatic symptoms at follow-up was available for 8,856 (73%) of the participants who provided satisfactory information at baseline, the follow-up rate being similar in those who initially did and did not have symptoms. Table 7 shows the number of somatic symptoms that they reported at follow-up, according to the number that were present at baseline. In general, participants reported similar numbers of symptoms at follow-up as at baseline, 6,677 (75%) having a change of zero or one in their symptom count. There were, however, notable exceptions. In particular, seven participants went from zero symptoms at baseline to seven at follow-up, and 19 changed to the same extent in the reverse direction. More detailed examination of the questionnaire responses for these 26 individuals indicated that for the most part, the changes represented substantial differences in the levels of distress reported from individual symptoms, and not simply a shift from their being "a little bit" to "moderately" distressing.

The 8,856 participants who provided complete information at both time-points reported a total of 10,326 somatic symptoms at baseline. Of these specific symptoms, 3,733 (36%) were

Table 4. Associations of multiple somatic symptoms with multi-site pain when one of the seven somatic symptoms was ignored.

Somatic symptom disregarded	Number of somatic symptoms														
	1		2		3		4		5		6		≥1 somatic symptom		
	PRR[a]	(95% CI)	PRR[a]	(95% CI)	PRR[a]	(95% CI)	PRR[a]	(95% CI)	PRR[a]	(95% CI)	PRR[a]	(95% CI)	PRR[a]	(95% CI)	PAF[b] (%)
Faintness or dizziness	2.4	(2.1–2.8)	3.9	(3.3–4.7)	5.1	(4.2–6.3)	5.2	(4.2–6.5)	5.8	(4.6–7.5)	5.7	(4.6–7.1)	3.7	(3.2–4.4)	57.6
Pains in heart or chest	2.5	(2.1–2.9)	4.1	(3.4–5.0)	5.0	(4.1–6.2)	5.4	(4.3–6.8)	5.8	(4.5–7.4)	5.9	(4.7–7.3)	3.8	(3.2, 4.5)	58.6
Nausea or upset stomach	2.5	(2.1–3.0)	4.2	(3.5–5.0)	4.8	(3.9–5.9)	5.5	(4.4–6.8)	5.6	(4.4–7.1)	5.4	(4.4–6.7)	3.8	(3.2–4.4)	57.0
Trouble getting breath	2.4	(2.1–2.7)	4.1	(3.4–5.0)	5.0	(4.1–6.0)	5.3	(4.3–6.6)	6.1	(4.8–7.7)	5.8	(4.6–7.2)	3.8	(3.2–4.4)	58.6
Hot or cold spells	2.5	(2.2–3.0)	4.3	(3.6–5.2)	4.8	(3.8–6.0)	5.3	(4.2–6.7)	5.6	(4.4–7.1)	5.1	(4.0–6.5)	3.8	(3.2–4.5)	56.7
Feeling weak in parts of your body	2.5	(2.1–2.9)	3.7	(3.1–4.3)	4.3	(3.6–5.2)	4.7	(3.8–5.8)	5.1	(4.1–6.5)	4.8	(3.9–5.9)	3.3	(2.9–3.9)	53.2
Numbness or tingling in parts of your body	2.5	(2.2–2.9)	3.8	(3.2–4.6)	4.2	(3.5–5.1)	4.8	(3.9–6.0)	4.8	(3.9–6.0)	5.1	(4.0–6.3)	3.4	(3.0–4.0)	54.4

[a] Prevalence rate ratio, adjusted for sex and age (in four 10-year strata), for pain at ≥4 vs. 0 anatomical sites in participants with the specified number of somatic symptoms compared with no somatic symptoms. The specified number of symptoms was from the total of six that remained when the symptom in the left-hand column was disregarded.

[b] Population attributable fraction

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again reported at follow-up, while 6,593 (64%) had resolved. On the other hand, 4,123 (52%) of a total of 7,856 symptoms at follow-up were new since baseline. Table 8 summarises the pair-wise associations between specific somatic symptoms at baseline and at follow-up. The highest

Table 5. Associations between number of somatic symptoms and sickness absence for >5 days in past 12 months for non-musculoskeletal reasons.

Number of somatic symptoms	Duration of sickness absence in past 12 months for reasons other than musculoskeletal pain					
	None	>5 days				
	N	N	PRR[a]	(95%CI)	PAF[b] (%)	(95%CI)
0	3,982	408	1			
1	1,377	225	1.4	(1.1–1.7)	5.1	(2.3–7.9)
2	863	200	1.8	(1.6–2.2)	7.7	(5.8–9.6)
3	453	135	2.3	(1.8–2.8)	6.3	(4.4–8.2)
4	266	104	2.8	(2.2–3.4)	5.5	(3.5–7.6)
5	154	60	2.7	(2.1–3.5)	3.2	(1.7–4.7)
6	70	34	2.9	(2.0–4.1)	1.9	(0.8–2.9)
7	44	28	3.2	(2.4–4.2)	1.6	(0.7–2.5)
≥1	3,227	786	1.9	(1.6–2.2)	30.4	(23.9–36.9)
≥3	987	361	2.5	(2.1–3.1)	18.4	(10.9–25.8)

[a] Prevalence rate ratio relative to no sickness absence in past 12 months for non-musculoskeletal reasons, adjusted for sex and age (in four 10-year strata)

[b] Population attributable fraction

doi:10.1371/journal.pone.0153748.t005

Table 6. Associations of multiple somatic symptoms with sickness absence for >5 days in past 12 months for non-musculoskeletal reasons when one of the seven somatic symptoms was ignored.

Somatic symptom disregarded	Number of somatic symptoms														
	1		2		3		4		5		6		≥1 somatic symptom		
	PRR[a]	(95% CI)	PRR[a]	(95% CI)	PRR[a]	(95% CI)	PRR[a]	(95% CI)	PRR[a]	(95% CI)	PRR[a]	(95% CI)	PRR[a]	(95% CI)	PAF[b] (%)
Faintness or dizziness	1.4	(1.2–1.6)	2.0	(1.7–2.3)	2.4	(1.9–3.0)	2.4	(1.9–3.1)	2.8	(2.1–3.8)	3.0	(2.3–3.9)	1.8	(1.6–2.1)	29.3
Pains in heart or chest	1.4	(1.2–1.7)	1.8	(1.6–2.1)	2.3	(1.9–2.8)	2.8	(2.2–3.5)	2.6	(2.0–3.3)	3.6	(2.7–4.9)	1.8	(1.6–2.2)	29.6
Nausea or upset stomach	1.4	(1.2–1.7)	1.9	(1.6–2.2)	2.4	(2.0–2.9)	2.7	(2.1–3.4)	2.6	(1.9–3.6)	2.9	(2.1–3.9)	1.8	(1.6–2.1)	28.0
Trouble getting breath	1.4	(1.2–1.6)	1.9	(1.6–2.2)	2.1	(1.7–2.7)	2.7	(2.2–3.3)	2.9	(2.1–3.8)	2.9	(2.1–3.9)	1.8	(1.6–2.1)	29.4
Hot or cold spells	1.6	(1.3–1.8)	2.0	(1.7–2.3)	2.5	(2.0–3.1)	2.7	(2.1–3.5)	2.9	(2.2–3.9)	2.9	(2.2–3.8)	2.0	(1.7–2.3)	30.4
Feeling weak in parts of your body	1.4	(1.2–1.6)	1.9	(1.6–2.3)	2.4	(2.0–3.0)	2.9	(2.3–3.6)	3.0	(2.1–4.1)	2.9	(2.2–3.8)	1.8	(1.6–2.1)	27.1
Numbness or tingling in parts of your body	1.5	(1.2–1.7)	2.0	(1.7–2.3)	2.7	(2.3–3.3)	2.6	(2.1–3.3)	2.5	(1.7–3.7)	3.1	(2.4–4.0)	1.9	(1.6–2.2)	29.5

[a] Prevalence rate ratio, adjusted for sex and age (in four 10-year strata), for sickness absence in the past 12 months for non-musculoskeletal reasons vs. 0 days of sickness absence in participants with the specified number of somatic symptoms compared with no somatic symptoms. The specified number of symptoms was from the total of six that remained when the symptom in the left-hand column was disregarded.

[b] Population attributable fraction

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odds ratios (3.6 to 6.6) were for continuing presence of the same symptom at follow-up as at baseline, but all odds ratios were ≥1.6, and most were ≥2.0.

Fig 1 shows the prevalence of different numbers of somatic symptoms at baseline by occupational group. There was major variation between the groups–for example, the prevalence of ≥3 somatic symptoms ranged from 1.3% among office workers in Pakistan and 4.2% in sugar cane cutters in Brazil to 38.1% in office workers in Costa Rica and 51.8% in manual workers in Costa Rica. Apart from the Brazilian sugar cane cutters, rates in South and Central America were all relatively high. The mean numbers of symptoms by occupational group showed greater similarity within than between countries (ICC = 15%). However, there was no consistent pattern by type of occupation (nurse, office worker or other).

Table 7. Number of somatic symptoms reported at follow-up according to number of somatic symptoms reported at baseline.

Number of symptoms at baseline	Number of symptoms at follow-up							
	0	1	2	3	4	5	6	7
0	3,329	622	235	107	49	18	10	7
1	885	479	216	108	47	15	2	0
2	452	293	217	101	52	21	12	2
3	230	151	137	98	54	16	14	4
4	141	71	81	75	47	29	19	5
5	51	31	40	41	26	17	7	5
6	20	12	18	16	13	16	9	5
7	19	13	5	10	5	11	8	7

Analysis was restricted to the 8,856 participants who provided complete information about somatic symptoms at both baseline and follow-up.

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Table 8. Pairwise associations between specific somatic symptoms at baseline and at follow-up.

Symptom at baseline	Symptom at follow-up						
	Faintness or dizziness (n = 741)	Pains in heart or chest (n = 542)	Nausea or upset stomach (n = 1,254)	Trouble getting breath (n = 558)	Hot or cold spells (n = 1,445)	Feeling weak in parts of body (n = 1,778)	Numbness or tingling in parts of body (n = 1,538)
Faintness or dizziness (n = 1,030)	5.0 (293)	2.6 (149)	2.4 (295)	2.1 (133)	2.1 (304)	2.3 (377)	2.5 (351)
Pains in heart or chest (n = 753)	2.6 (155)	5.6 (182)	2.0 (196)	2.6 (115)	1.8 (216)	2.0 (264)	2.1 (252)
Nausea or upset stomach (n = 1,719)	2.6 (287)	2.0 (190)	3.6 (545)	1.7 (179)	1.6 (421)	2.0 (556)	1.7 (462)
Trouble getting breath (n = 748)	2.6 (148)	3.2 (132)	2.1 (202)	6.6 (199)	1.8 (215)	2.3 (286)	2.2 (253)
Hot or cold spells (n = 1,833)	2.2 (285)	2.1 (219)	2.0 (438)	1.9 (208)	3.9 (709)	2.1 (620)	2.0 (557)
Feeling weak in parts of body (n = 2,317)	2.6 (361)	2.4 (263)	2.1 (538)	2.2 (265)	2.0 (611)	4.3 (983)	2.9 (760)
Numbness or tingling in parts of body (n = 1,926)	2.5 (306)	2.7 (249)	2.0 (452)	1.9 (220)	1.9 (534)	2.7 (729)	5.1 (822)

Associations are summarised by odds ratios adjusted for sex and age (in 10-year strata), with the number of participants reporting both symptoms in brackets. Analysis was restricted to the 8,856 participants who provided complete information about somatic symptoms at both baseline and follow-up.

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To explore whether any occupational groups displayed a distinct profile of somatic symptoms, we compared the proportionate frequency of specific symptoms after standardisation for sex and age. The standardised proportions ranged from 0 for hot or cold spells in Brazilian sugar cane cutters and 0.15 for hot or cold spells in Sri Lankan postal workers to 1.98 for nausea or upset stomach in Japanese sales personnel and 2.10 for hot or cold spells in Pakistani postal workers. However, the large majority were between 0.67 and 1.5. The most salient patterns by country were high ratios for trouble getting breath in Brazil (1.28–1.56); low ratios for hot or cold spells in Greece (0.37–0.73); high ratios for faintness or dizziness (1.73 and 1.75) and low ratios for feeling weak (0.31 and 0.49) in Estonia; low ratios for pains in the heart or chest in Lebanon (0.42–0.63); low ratios for each of faintness or dizziness (0.58–0.72), pains in the heart or chest (0.23–0.78) and trouble getting breath (0.28–0.80), and high ratios for hot or cold spells (1.44–2.10) in Pakistan; high ratios for nausea or upset stomach (1.17–1.98) and low ratios for trouble getting breath (0.24–0.53) in Japan; and high ratios for pains in the heart or chest in South Africa (1.57 and 1.77). Further details are given in Table 9.

In a mutually adjusted analysis of the cross-sectional association between personal characteristics and somatising tendency (pragmatically specified as report of $\geq$3 somatic symptoms), there was a significantly elevated risk with female sex (PRR 1.8, 95%CI 1.5–2.1), and a weak but significant relationship to smoking habits (PRRs of 1.3 and 1.2 for current and ex- as compared with non-smokers). However, there was no association with age of finishing full-time education (data not shown).

Discussion

Within our large study sample, the seven somatic complaints that we examined were all mutually associated, such that report of multiple symptoms was much more frequent than would have been expected had their occurrence been unrelated. However, no cut-point in the number

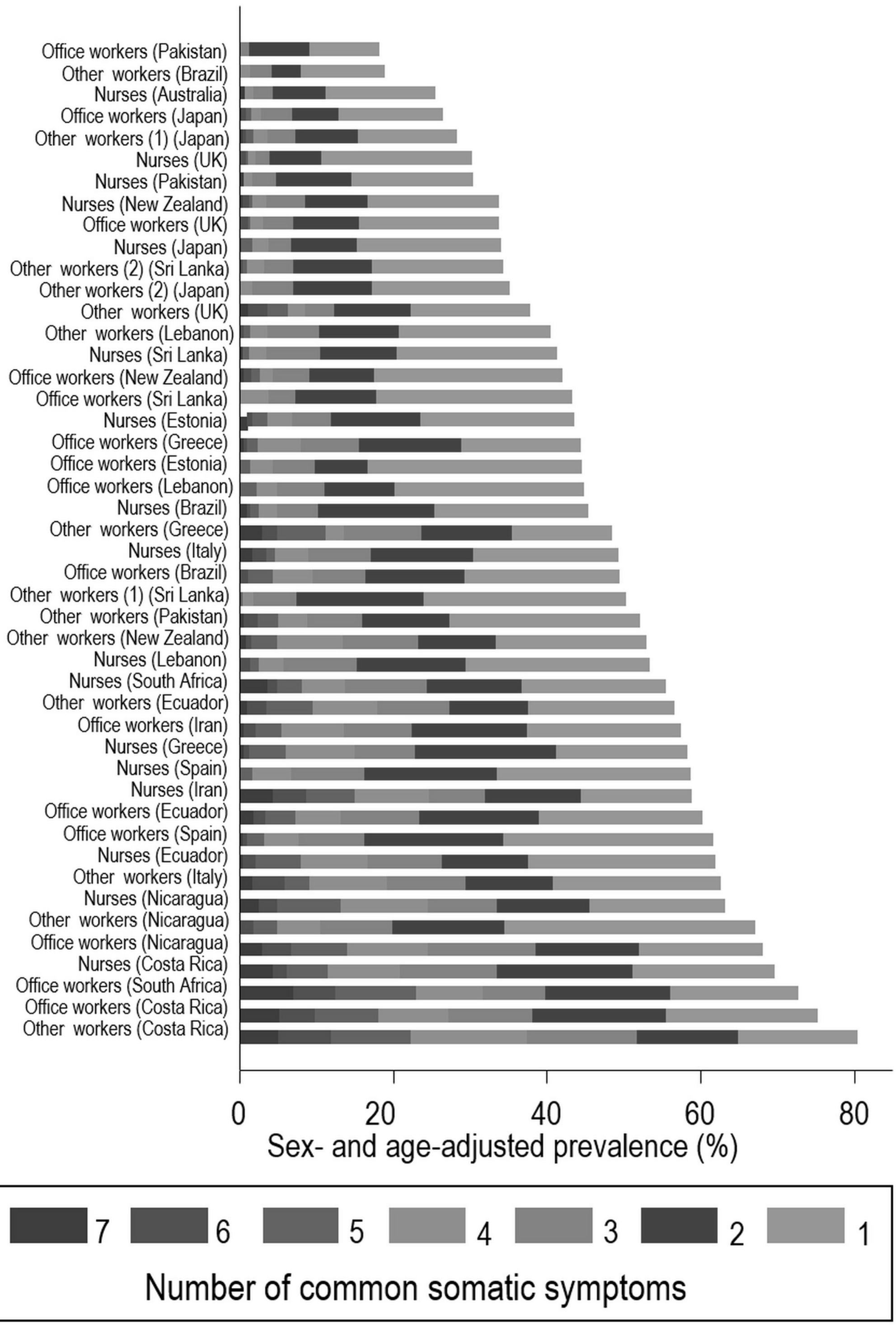

Fig 1. Frequency of somatic symptoms by occupational group.

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Table 9. Standardised proportions of specific symptoms by occupational group.

Occupational group	Symptom						
	Faintness or dizziness	Pains in heart or chest	Nausea or upset stomach	Trouble getting breath	Hot or cold spells	Feeling weak in parts of your body	Numbness or tingling in parts of your body
Brazil							
Nurses	0.58	1.03	0.77	1.28	0.80	1.06	1.43
Office workers	0.60	1.43	0.69	1.56	0.89	0.94	1.21
Other workers	1.32	1.27	0.72	1.54	0.00	0.83	1.89
Ecuador							
Nurses	1.13	0.94	1.00	0.63	1.29	0.96	0.84
Office workers	0.63	1.17	1.08	0.87	1.05	1.02	1.05
Other workers	1.06	1.37	0.91	1.12	1.11	0.98	0.75
Costa Rica							
Nurses	0.56	0.94	1.01	0.92	1.12	1.02	1.16
Office workers	0.71	1.02	1.12	1.16	1.15	0.83	1.04
Other workers	0.96	1.18	0.88	1.03	0.90	0.95	1.20
Nicaragua							
Nurses	0.78	0.80	1.03	0.89	1.12	0.91	1.19
Office workers	0.70	1.04	0.89	1.17	1.12	0.95	1.15
Other workers	0.53	0.54	0.83	1.52	1.23	1.07	1.16
UK							
Nurses	0.92	1.28	1.13	0.75	1.18	0.90	0.86
Office workers	1.05	1.06	1.05	1.08	1.05	0.96	0.88
Other workers	1.31	1.14	1.00	1.12	1.07	0.95	0.75
Spain							
Nurses	0.73	0.52	0.93	0.76	0.64	1.56	1.23
Office workers	0.66	0.56	0.89	0.88	1.17	1.24	1.09
Italy							
Nurses	1.16	1.06	1.24	1.18	0.87	0.88	0.86
Other workers	0.94	0.87	0.96	1.44	0.83	1.05	1.06
Greece							
Nurses	1.22	0.74	0.98	0.93	0.37	1.20	1.34
Office workers	1.08	1.18	0.96	0.63	0.73	1.11	1.19
Other workers	1.39	0.91	0.81	1.45	0.58	1.10	1.05
Estonia							
Nurses	1.75	1.77	0.84	1.15	1.03	0.49	0.90
Office workers	1.73	1.29	0.91	1.96	0.95	0.31	1.01
Lebanon							
Nurses	1.07	0.42	1.35	1.14	0.63	1.13	0.96
Office workers	0.71	0.48	1.25	1.68	0.57	1.15	1.11
Other workers	0.95	0.63	0.70	1.44	1.21	0.89	1.29
Iran							
Nurses	1.50	1.32	0.84	1.23	0.90	1.01	0.68
Office workers	1.86	1.05	0.38	0.74	1.40	1.00	0.79
Pakistan							
Nurses	0.58	0.36	0.50	0.36	1.44	1.47	1.54
Office workers	0.64	0.23	0.83	0.28	1.86	1.43	0.68
Other workers	0.72	0.78	0.72	0.80	2.10	1.09	0.57

(*Continued*)

Table 9. (*Continued*)

Occupational group	Symptom						
	Faintness or dizziness	Pains in heart or chest	Nausea or upset stomach	Trouble getting breath	Hot or cold spells	Feeling weak in parts of your body	Numbness or tingling in parts of your body
Sri Lanka							
Nurses	1.07	0.67	1.08	1.51	1.41	0.64	0.80
Office workers	0.76	1.11	1.01	0.87	1.33	0.72	1.18
Other workers (1)	0.83	1.26	0.80	0.99	0.15	1.40	1.20
Other workers (2)	0.82	1.59	1.05	0.79	1.15	0.95	0.79
Japan							
Nurses	1.38	0.87	1.56	0.53	0.90	0.85	0.66
Office workers	1.70	0.80	1.25	0.24	1.14	0.84	0.88
Other workers (1)	1.34	0.80	1.17	0.42	0.94	1.13	0.91
Other workers (2)	1.13	0.68	1.98	0.35	1.05	0.84	0.56
South Africa							
Nurses	1.20	1.57	0.83	1.16	1.06	0.83	0.88
Office workers	1.04	1.77	1.06	1.22	0.98	0.71	0.84
Australia							
Nurses	1.08	0.49	1.33	1.03	0.87	1.07	0.92
New Zealand							
Nurses	0.90	1.09	1.15	0.49	1.21	0.97	0.91
Office workers	0.62	0.58	1.36	0.83	1.12	1.05	0.97
Other workers	0.84	0.85	1.05	0.92	1.08	1.15	0.88

Standardised proportions were calculated as $O/\sum_i(n_i * S_i/N_i)$ where O was the observed frequency of the specified symptom in the occupational group, and within the i^{th} of 8 strata of sex and 10-year age band, n_i was the total number of symptom reports (any of the seven symptoms) in the occupational group, S_i was the number of reports of the specified symptom in all occupational groups combined, and N_i was the total number of symptom reports (any of the seven symptoms) in all occupational groups combined.

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of reported symptoms distinguished unequivocally between people with and without a somatising syndrome. Rather, there appeared to be a gradation in degrees of tendency to somatise. In most individuals, the level of somatising tendency (as assessed by the questionnaire) was little changed after a follow-up interval of approximately 14 months, although the specific symptoms reported at follow-up often differed from those at baseline. Tendency to somatise was more common in women than men, especially at older ages, and after allowance for sex and age, it varied markedly across the 46 occupational groups studied, with greater similarities within than between countries. It was weakly associated with smoking, but not with level of education.

As well as the size, geographical spread and cultural diversity of the study sample, our investigation benefitted from high response rates. However, it was limited to adults of working age, and the findings cannot necessarily be extrapolated to other age groups. It was also restricted to selected occupational groups, although apart perhaps from sugar cane cutters in Brazil, it seems unlikely that these will have been highly unrepresentative of the wider working populations in participating countries.

Somatising tendency was assessed through seven questions taken from the Brief Symptom Inventory, which has been established as a valid and reliable instrument [22] with the ability to predict future health outcomes in longitudinal investigations [6–8]. Moreover, where it was necessary to translate the questionnaire into local languages, care was taken to check accuracy through independent back-translation. Nevertheless, it is possible that symptoms were understood differently across varied cultural settings. Such variation may have contributed to differences in prevalence between countries, but would not explain associations with other variables measured at individual level in analyses that adjusted for possible clustering by job group.

We did not have information about personality traits or about other medical conditions such as cancer, which may have caused some of the symptoms that distressed participants. However, since our study sample comprised adults in active employment, the prevalence of serious co-morbidity will have been low, and should not have impacted importantly on our conclusions.

Understanding of terms for pain may have varied between participants speaking different languages, but the anatomical location of symptoms should have been unambiguous, since it was defined pictorially. Errors of interpretation are less likely to have occurred for other variables such as history of sickness absence, smoking habits and educational level, although they may have been liable to inaccurate recall. Provided inaccuracies were not differential in relation to somatising tendency, any resultant bias in associations with somatising tendency will have been towards the null.

Much of the literature on somatisation has focused on medically unexplained somatic symptoms as a reason for presentation to medical care, and a manifestation of hidden psychiatric morbidity. As defined in the tenth revision of the International Classification of Diseases (ICD10), somatisation disorder is generally infrequent, with prevalence rates among adults aged 18–65 years in a cross-cultural study of 14 countries mostly less than 2% [23]. However, our interest was in the wider spectrum of distress from common somatic symptoms, not necessarily leading to medical consultation of themselves, but collectively associated with other aspects of health and health-related behaviour. By limiting our enquiry to symptoms in the past week, we reduced the potential for errors in recall, which can be a problem when longer periods are considered [24].

Our results confirm that report of multiple distressing somatic symptoms constitutes a syndrome, the co-occurrence of symptoms being much more frequent than would be expected by chance. However, there was no clear dichotomy between people with and without somatising tendency. Thus, the strength of associations, both with multi-site pain and with sickness absence for non-musculoskeletal reasons, increased progressively with the number of symptoms reported, at least up to five. Because these associations were cross-sectional, they cannot necessarily be interpreted as causal, although longitudinal studies have indicated that people who complain of common somatic symptoms are more likely to develop multisite musculoskeletal pain subsequently [19,20]. We also found that all seven of the symptoms investigated contributed to the measurement of somatising tendency, with smaller attributable fractions for multi-site pain and non-musculoskeletal sickness absence when any one of the symptoms was disregarded. However, the differences in PAFs were generally small, and if resources were limited, it is likely that little would be lost if any one of the seven symptoms were omitted from the question set.

Follow-up of participants after approximately 14 months demonstrated that levels of somatising tendency were fairly stable within individuals over that timescale, and the observation that this occurred despite changes in the specific symptoms reported is evidence that the consistency reflects a continuing general predisposition to be aware of and report physical symptoms, rather than persistence of specific underlying disease. A similar pattern has been found in earlier longitudinal studies [24]. It is notable, however, that a small minority of participants exhibited major changes in their degree of somatising tendency, suggesting that it is not entirely a fixed trait, and raising the possibility that it might in some cases be amenable to intervention. Another possibility is that these large changes reflected the development or resolution of co-morbidity.

The higher frequency of somatic symptoms among women than men accords with other studies [25–27]. It has been postulated that the imbalance may reflect innate differences in somatic and visceral perception; differences in symptom labelling, description and reporting; or a greater willingness of women to acknowledge and disclose discomfort [25]. It could also arise from a higher prevalence of depression in women.

Somatisation has also been reported to occur more commonly at older ages [23]. We too found a positive relationship to age in women, although in men, the prevalence of somatic symptoms was highest at younger ages. Because our analysis was cross-sectional, it was not possible to distinguish effects of age from trends across birth cohorts. However, the higher prevalence of hot or cold flushes among older women may have been a physiological effect of age.

The large differences between occupational groups and countries in the prevalence and degree of somatising tendency were apparent even after adjustment for differences in sex and age. As already discussed, the variation may have been, at least in part, a linguistic artefact. However, earlier research using different methods has also indicated unusually high rates of somatisation in South America [23]. In that study, there was no evidence that somatising patients from South America had a lower prevalence of co-occurring depression or generalised anxiety disorder, which suggests that their somatisation was not a manifestation of occult mental illness. Perhaps more likely is a culturally determined difference in the perception of bodily sensations and the importance that is attached to them, or in willingness to report them when they occur. There was also variation between countries in the relative frequency of specific somatic symptoms, but to a lesser extent.

Somatisation has previously been linked with an absence of formal education [23], but after allowance for sex, age and occupational group, we found no relationship to level of education. This may have been because within occupational groups there was too little heterogeneity for an effect to be discernible. We did, however, find a weak association with smoking, which is consistent with an earlier study in Finnish adolescents [28].

In summary, our study supports the use of questions from the Brief Symptom Inventory as a method for measuring tendency to somatise, each of the seven questions contributing to its assessment. The findings indicate that somatising tendency should be regarded as a quantifiable characteristic that exhibits an exposure-response relationship in its association with other health measures, and appears to be fairly stable over an interval of approximately one year, although the specific symptoms that individuals report frequently vary over time. It is more common in women than in men, especially at older ages, and its prevalence varies between countries with higher rates in South and Central America.

Given its potential to explain differences in disability and in economically important outcomes such as sickness absence from work, there is a need to understand further what drives somatising tendency, and whether and how it might be modified at a population level. There is evidence, for example, that it tracks across generations [29], and it may be a trait which is acquired early in life. Thus, there is a need for further research to establish how it evolves at younger ages, what influences its development, and also how constant it remains over longer follow-up periods.

Supporting Information

S1 Appendix. Committees which provided ethical approval for the CUPID study.
(DOCX)

S1 Dataset. Supporting Dataset.
(DTA)

S1 Metadata. Metadata.
(XLSX)

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Author Contributions

Conceived and designed the experiments: DC SVP. Performed the experiments: SVP DC GN KTP VEF RH LHB SAF DG AC MB ES EM RRH FS MMK SSPW KM BN MRS HH KC

LMMS MHM FH RF NH MVM LAQ MR ECH CS JMM GD FGB MC MMF ACP LC PB MK KO TF AS RJP-J NS ARW NY HLK VCWH DMU SD DM PH AG EJSV. Analyzed the data: GN DC KWB KTP. Contributed reagents/materials/analysis tools: N/A. Wrote the paper: SVP DC. Provided feedback on the initial draft manuscript and agreed the final changes: GN KTP KWB VEF RH LHB SAF DG AC MB ES EM RRH FS MMK SSPW KM BN MRS HH KC LMMS MHM FH RF NH MVM LAQ MR ECH CS JMM GD FGB MC MMF ACP LC PB MK KO TF AS RJP-J NS ARW NY HLK VCWH DMU SD DM PH AG EJSV.

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Original article

A population approach to analyze the effectiveness of a back extension exercise "One Stretch" in patients with low back pain: A replication study

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ABSTRACT

Background: We examined the effectiveness of an intervention using a standing back extension exercise called "One Stretch", based on the McKenzie method, in improving or preventing low back pain and disability in Japanese care workers.
Methods: We conducted a non-randomized controlled trial in Japan. Care workers in the intervention group received an exercise manual and a 30-minute seminar on low back pain and were encouraged to exercise in groups, while care workers in a control group were given only the manual. All care workers answered questionnaires at baseline and after one year on the subjective improvement in low back pain, whether they had had a medical consultation for low back pain, and the exercise compliance. Low back pain with disability was assessed by the Oswestry Disability Index.
Results: Participants included 89 workers in the intervention group and 78 in the control group. Background characteristics did not differ significantly between the two groups. Compared to the control group, a greater number of care workers in the intervention group showed improvements in low back pain or prevented it, did not have a medical consultation for low back pain, and exercised regularly. Furthermore, significantly fewer care workers in the intervention group suffered from low back pain with disability by the end of the study period than in the control group.
Conclusion: The population approach about the exercise "One Stretch" led to better compliance with the exercise, and was effective for improving or preventing low back pain and in decreasing the likelihood of having a medical consultation for low back pain.

1. Introduction

Low back pain (LBP) is a major health problem, particularly in industrialized countries, and has affected people's lives and livelihood in various ways. To reduce the socioeconomic impact of LBP, it is important to prevent people without LBP symptoms from developing them. Physical exercises have been recommended as one means of LBP prevention, although there is as yet insufficient evidence for advocating any specific type or intensity of exercise [1].

McKenzie, who introduced a method of classifying LBP by subgroups, recommends extension exercises because the posterior displacement of the nucleus via such exercises can relieve LBP [2]. The McKenzie method involves classifying patients into specific subgroups primarily based on their symptomatic and mechanical responses to mechanical loadings. Most individuals with LBP can benefit in a short period from the back extension loading strategy, the theoretical explanation of which is based on the disc mode. This model proposes that posterior displacement of the nucleus can be

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reduced via deliberate extension loading. Reducing how much the nucleus is displaced may result in decreased LBP. A meta-analysis regarding the McKenzie method concluded that this method may be effective for acute LBP patients; however, the magnitude of benefit may not be considered clinically worthwhile, and insufficient evidence exists for chronic LBP patients. Furthermore, the effectiveness of the classification-based McKenzie therapy has not yet been estimated [2].

The severity of LBP is positively correlated with disability, as shown by Von Korff et al. [3], and the present goal of LBP management is to become or remain free from LBP with disability. In Japan, in addition to an inadequate number of care workers and poor working environments for these, an increasing number of care workers are suffering from LBP with disability, which is a serious problem.

Therefore, we conducted an intervention trial utilizing a simple daily back extension exercise for LBP based on the McKenzie method called "One Stretch" for relieving LBP; however, LBP in the current study was not necessarily assumed to indicate discogenic LBP. Furthermore, there is insufficient evidence for the McKenzie method in treating chronic LBP patients, as noted above. Previously, this exercise was evaluated in a trial with 166 care workers [4], and the results indicated that the intervention group showed a greater improvement in objectively assessed LBP than did the control group. However, this study had the limitation in terms of the generalizability of the effects. Specifically, the intervention was delivered by a single individual, who was also one of the researchers involved in developing the intervention. Thus, a replication of this intervention in a different study center and conducted by someone outside the original development team is necessary. If similar effects were found, it would establish that this intervention of the population approach and the exercise "One Stretch" itself were responsible for the improvements, rather than the person delivering it, and that the intervention is generalizable across settings and populations.

2. Subjects and methods

2.1. Study population

This study was conducted at three health care facilities for the elderly in Nagano Prefecture, Japan. Eligible participants were Japanese care workers who worked at those facilities and supported the elderly in need of care. We excluded workers who would have had difficulty participating due to medical (e.g. spinal stenosis, rheumatoid arthritis, and ankylosing spondylitis) or other personal reasons. Furthermore, we excluded participants who did not complete the questionnaires at end of the 1-year study period. Written informed consent was obtained from all participants.

This study was approved by the medical/ethics review board of Kanto Rosai Hospital. We registered our study (ID: UMIN000006688) in the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR).

2.2. Study design

This was a non-randomized controlled trial. Participants who worked at one health care facility were assigned to the control group and those at the other two facilities were assigned to the intervention group. The health care facility of the control group and those associated with the intervention group did not exhibit any differences with respect to the number of care workers, the age and sex ratio of care workers, the number of beds, the care need score of patients, the ratio of disabled patients, and the ratio of patients with dementia. All participants received an exercise manual, but only the intervention group received a 30-min seminar. The exercise manual described how to do the standing back extension exercise One Stretch (shown in Fig. 1). This exercise is an active extension of the back that is commonly used in physical therapy and is based on the exercises used for treating derangement syndrome, one of the subgroups classified by the McKenzie method [2]. The manual also included evidence-based information for treatment and prevention of LBP, including self-management and risk factors (e.g., psychosocial factors and fear-avoidance). The 30-min seminar was delivered by an orthopedist, and merely comprised a detailed explanation of the exercise manual and the One Stretch exercise.

Participants were asked to do this exercise regularly. To promote regular exercise in the intervention group, we encouraged them to perform it in groups. Specifically, the care workers in the intervention group performed the exercise in a group at the daily meeting in the health care facility. This approach spanned the entire study period.

2.3. Data collection

At baseline and end of the 1-year study period, data were collected using a self-administrated questionnaire. The baseline questionnaire assessed the following: age, sex, body mass index (BMI), smoking habit, whether they had a medical consultation for LBP (yes or no) at baseline, and the severity of LBP in the previous month. The severity of LBP was evaluated using Von Korff's grading system: 1) no pain, 2) LBP that does not interfere with work, 3) LBP that interferes with work, and 4) LBP that interferes with work such that it leads to sick leave [3]. We defined pain localized between the costal margin and the inferior gluteal folds as LBP [5]; to ensure that participants understood what we meant by LBP, we provided a diagram of LBP in the questionnaire. We also determined if participants had LBP with disability using the Oswestry Disability Index (ODI) [6]. In this analysis, we set the ODI cut-off value as 12 as per previous findings on the topic [7].

The questionnaire at the end of the study period assessed subjective improvement in LBP from baseline (improved, no change, or worsened), whether they had a medical consultation for LBP (yes or no) at the end of the study period, and overall compliance with the exercise during the study period (good or poor). Compliance was evaluated using self-reported answers. Participants who performed the given exercise at least once during their working day were defined as having "good compliance". Participants were asked to record whether they performed the exercise each day to evaluate overall compliance with the exercise during the study period.

In order to evaluate the effectiveness of the population approach, we compared results of the intervention group and the control group. Further, in order to evaluate the effectiveness of the "One Stretch" exercise itself, we compared the post-intervention subjective improvement in LBP against exercise compliance in both groups.

2.4. Statistical analysis

Descriptive statistics were determined and presented as means and standard deviations (SDs) or frequencies and percentages. Between-group differences in baseline characteristics were evaluated by using the χ^2 test or the Cochran–Armitage test for categorical variables and Student's t-test for continuous variables. Whether they had a medical consultation for LBP and the compliance with the exercise were evaluated by using the χ^2 test, and subjective improvement in LBP was evaluated by using the Cochran–Armitage test. The association between the intervention and the subjective improvement in LBP from baseline was evaluated using the Cochran–Mantel–Haenszel test with stratification according to levels of exercise compliance. All statistical tests were two-tailed and conducted with a significance level of 0.05.

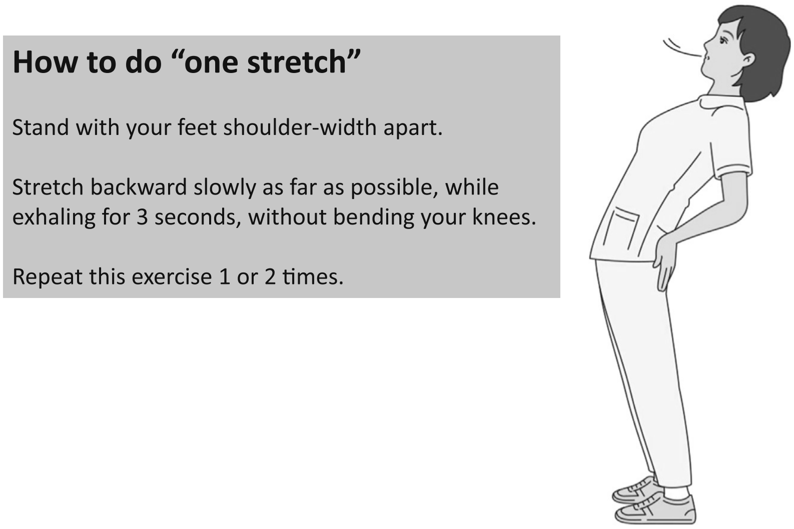

Fig. 1. Example of standing back extension “One Stretch”.

3. Results

A total of 167 care workers participated in this study and were assigned to either the intervention (n = 89) or the control group (n = 78). The mean age of the intervention group was 37.5 ± 12.4 years; 16.9% were men and 83.1% were women. The control group mean age was 37.6 ± 11.6 years, and 20.5% were men and 79.5% were women. The baseline characteristics of the groups are shown in Table 1. There were no significant differences in any characteristic, including the severity of LBP, and ODI between the two groups.

The post-intervention evaluations for the groups are shown in Table 2. Compared with the control group, the intervention group had a higher proportion of care workers who showed improvements in LBP, a lower proportion who had a medical consultation for LBP at the end of study period, and better compliance with the exercise. These differences were statistically significant ($P = 0.0001$, $P = 0.007$, and $P < 0.0001$, respectively). The proportion of participants in the intervention group with an ODI of greater than 12 at the end of the study period was less than that in the control group ($P = 0.04$); there were no significant differences between the groups at baseline.

The subjective improvement in LBP from baseline, compared with the pre-intervention severity of LBP, is shown in Table 3. Those from the intervention group having LBP that did not interfere with work showed a higher proportion of improvement in LBP, compared with those in the control group. The subjective improvement in LBP from baseline, according to exercise compliance, is shown in Table 4. Participants in the intervention group

Table 2
Post-intervention evaluations for intervention and control groups.

	Intervention (n = 89)	Control (n = 78)	*P*
Subjective improvement in LBP			*0.0001
Improved	27 (30.3)	6 (7.7)	
No change	25 (28.1)	44 (56.4)	
Worsened	5 (5.6)	9 (11.5)	
Medical consultation (yes)			
At baseline	9 (10.1)	16 (20.5)	0.06
At post-intervention	3 (3.4)	12 (15.4)	*0.007
Exercise compliance			*<0.0001
Good	47 (52.8)	13 (16.6)	
Poor	23 (25.8)	54 (69.2)	
ODI ≥ 12			
At baseline	30 (33.7)	32 (41.0)	0.33
At post-intervention	26 (29.2)	37 (47.4)	*0.04

Data are shown as number of participants (%). *: $P < 0.05$.
ODI, Oswestry Disability Index; LBP, low back pain.

Table 1
Baseline characteristics of the intervention and control groups.

	Intervention (n = 89)	Control (n = 78)	*P*
Age	37.5 ± 12.4	37.6 ± 11.6	0.97
Women	74 (83.1)	62 (79.5)	0.56
BMI	22.5 ± 3.8	22.3 ± 3.5	0.74
Smoking habit	39 (43.8)	37 (47.4)	0.28
Medical consultation (yes)	9 (10.1)	16 (20.5)	0.06
Severity of LBP in the previous 1 month			0.37
No pain	26 (29.2)	24 (30.8)	
LBP not interfering with work	54 (60.7)	40 (51.3)	
LBP interfering with work	4 (4.5)	11 (14.1)	
LBP interfering with work such that it leads to sick leave	1 (1.1)	1 (1.3)	
ODI	9.8 ± 1.0	11.5 ± 1.1	0.28
ODI ≥ 12	30 (33.7)	32 (41.0)	0.33

Data are shown as mean ± SD or number of participants (%).
ODI, Oswestry Disability Index; LBP, low back pain.

Table 3
Subjective improvement in LBP from baseline contrasted against the pre-intervention severity of LBP in the intervention and control groups.

Pre-intervention severity of LBP		n	Subjective improvement		
			Improved	No change	Worsened
No pain	Intervention	13	6 (46.2)	6 (46.2)	1 (7.7)
	Control	15	0 (0)	11 (73.3)	4 (26.7)
LBP not interfering with work	Intervention	40	20 (50.0)	17 (42.5)	3 (7.5)
	Control	33	3 (9.1)	27 (81.8)	3 (9.1)
LBP interfering with work such that it may or may not require sick leave	Intervention	3	0 (0)	2 (66.7)	1 (33.3)
	Control	9	3 (33.3)	4 (44.4)	2 (22.2)

Data are shown as number of participants (%).

Table 4
Subjective improvement in LBP from baseline contrasted against exercise compliance in the intervention and control groups.

Compliance		n	Improved	No change	Worsened
Good	Intervention	38	22 (57.9)	12 (31.6)	4 (10.5)
	Control	10	3 (30.0)	7 (70.0)	0 (0)
Poor	Intervention	17	4 (23.5)	12 (70.6)	1 (7.5)
	Control	48	3 (6.3)	37 (77.1)	8 (16.7)

Data are shown as number of participants (%).

that had good compliance showed a tendency towards greater subjective improvement in LBP, although this tendency did not reach statistical significance ($P = 0.054$).

4. Discussions

There were no significant differences in baseline characteristics between the intervention and control groups. The number of participants was almost equivalent to the previous study investigating this exercise [4], although the proportion of women was higher in the current study than in the previous study. The proportion of participants who had had a medical consultation for LBP at baseline, in both the intervention and control groups, was about ten times or more that of the Japanese general population, which was about 0.5% [8]. Thus, we might infer that care workers are disproportionately likely to have a medical consultation for LBP. The ODI at baseline in both groups was higher than the normative score of the ODI (8.73) [7], indicating that care workers were more likely to have LBP with disability. Specifically, the proportions of participants with an ODI $\geq$ 12 at baseline in intervention and control groups were 33.7% and 41.0%, respectively. However, for both groups, the proportion of participants who reported a subjective severity of LBP as "interferes with work" was lower than the proportion of participants with an ODI $\geq$ 12. Thus, it is possible that some participants who answered that their LBP severity was "does not interfere with work" might actually have LBP with disability.

In the subjective evaluations of the improvement, the intervention group had a higher proportion of care workers who had "improved" LBP, especially in those having LBP that did not interfere with work, compared to the control group. Furthermore, we noticed that subjective evaluations of "no change" included care workers without LBP. Six care workers who did not report LBP prior to intervention expressed an improvement in LBP post-intervention. In this case, it is possible that these 6 individuals forgot their initial response of "no pain." Conversely, it is also possible that they were not suffering from LBP at the time of the post-intervention questionnaire. Therefore, we regarded the proportion of participants responding with "improved" or "no pain" following an original response of "no pain" as individuals in whom the exercises prevented the development of LBP. These findings suggest that the population approach of the standing back extension exercise "One Stretch" is effective for improving and preventing LBP. This result is similar to what the previously trial on this exercise [4]. The intervention group had better compliance with the exercise than did the control group, which suggests that a population approach can encourage better compliance with the exercise. Generally, a population health approach is considered a powerful preventive strategy affecting causal behavior in health care activities [9]. This matches the present result regarding prevented LBP. It has been reported that some individuals need an individual approach in order to adopt preventive behaviors and that both population and individual approaches must complement each other [10]; however, individual approaches were not used in the current study.

A lower proportion of the intervention group had a medical consultation for LBP at the end of the study period. This finding is perhaps due not only to the subjective improvements in LBP but also to the fact that the intervention group participants had acquired a technique and conception for self-management of their LBP. Therefore, the intervention can be said to decrease the treatment costs for LBP, which is beneficial for both individuals and society.

Good exercise compliance was associated with a greater degree of improvement in LBP. This suggests that the "One Stretch" exercise is effective for improving and preventing LBP. That is also similar to the previous study on the One Stretch exercise [4]. Several other studies have supported the effectiveness of extension exercises for LBP. Long et al. [11] found that patients randomized to favorable directional preference exercises, consisting mostly of extension exercises, showed significant improvements in LBP compared to those randomized to opposite or mid-range movements. In a randomized controlled trial in which military conscripts performed either extension in lying exercises or a control group, the intervention group showed a significantly lower prevalence of LBP and care seeking for LBP compared to the control group [12]. Additionally, the extension approach inhibited developing back problems in the young male conscripts. This is similar to our study, even if there were differences in age, sex, and an exact posture of extensions. One of a possible mechanism for the clinical improvements seen in the present study was highlighted in a previous study using kinematic magnetic resonance imaging. Specifically, slightly degenerated intervertebral discs moved in a posterior direction during flexion and in an anterior direction during extension [13]. However, results of this study have shown that the effectiveness of the "One Stretch" exercise for LBP was not limited to discogenic LBP.

The proportion of participants with an ODI $\geq$ 12 in the intervention group at the end of the study period was lower than that in the control group, whereas there was no significant difference between the groups at baseline. This result indicates that LBP with disability can be reduced by the intervention. At present, LBP is prevalent in all adult populations, but only a few subjects become disabled. However, these patients are responsible for most of the treatment costs for LBP [14]. As noted before, the severity of LBP correlates with disability [3] and the present goal of LBP management is to become or remain free from LBP with disability; as such, efforts to prevent LBP with disability instead of LBP in general are likely to be more effective and efficient. The intervention in the current study could be effective in terms of the aforementioned purpose. As such, the objective evaluation by the ODI is perhaps underestimated compared to the subjective improvement.

There were several limitations to this study. First, the questionnaire contained retrospective questions wherein participants assessed their LBP condition after one year; thus, the possibility for recall bias must be considered. Second, the sample was comparatively small. Due to the nature of the study, clustered randomized trials with adequate sample sizes are needed for evaluating the intervention. Thus, the generalizability of findings is limited and the findings should be interpreted with caution. We will perform further investigations of this topic in large-scale randomized controlled trials.

5. Conclusion

The population approach about the exercise "One Stretch" led to better compliance with the exercise, and was effective for improving or preventing LBP and in decreasing the likelihood of having a medical consultation for LBP. It is likely that the population approach about daily practice of this simple exercise and the exercise itself can benefit our society, especially in industrial health.

Conflict of interest

The authors declare that they have no conflict of interest.

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RESEARCH ARTICLE

Psychometric Properties of the Japanese Version of the STarT Back Tool in Patients with Low Back Pain

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Abstract

Background and Objective

The STarT Back Tool uses prognostic indicators to classify patients with low back pain into three risk groups to guide early secondary prevention in primary care. The present study aimed to evaluate the psychometric properties of the Japanese version of the tool (STarT-J).

Methods

An online survey was conducted among Japanese patients with low back pain aged 20–64 years. Reliability was assessed by examining the internal consistency of the overall and psychosocial subscales using Cronbach's alpha coefficients. Spearman's correlation coefficients were used to evaluate the concurrent validity between the STarT-J total score/psychosocial subscore and standard reference questionnaires. Discriminant validity was evaluated by calculating the area under the curves (AUCs) for the total and psychosocial subscale scores against standard reference cases. Known-groups validity was assessed by examining the relationship between low back pain-related disability and STarT-J scores.

Results

The analysis included data for 2000 Japanese patients with low back pain; the mean (standard deviation [SD]) age was 47.7 (9.3) years, and 54.1% were male. The mean (SD) STarT-J score was 2.2 (2.1). The Cronbach's alpha coefficient was 0.75 for the overall scale and 0.66 for the psychosocial subscale. Spearman's correlation coefficients ranged from 0.30 to 0.59, demonstrating moderate to strong concurrent validity. The AUCs for the total score ranged from 0.65 to 0.83, mostly demonstrating acceptable discriminative ability. For known-groups validity, participants with more somatic symptoms had higher total scores. Those in higher STarT-J risk groups had experienced more low back pain-related absences.

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Conclusions

The overall STarT-J scale was internally consistent and had acceptable concurrent, discriminant, and known-groups validity. The STarT-J can be used with Japanese patients with low back pain.

Introduction

Low back pain (LBP) is a major musculoskeletal problem in the general population from childhood to older adulthood, affecting more than 632 million people worldwide [1]. The 2010 Global Burden of Diseases, Injuries, and Risk Factors Study reported that LBP was the leading cause of disability among 291 diseases and injuries globally, and LBP ranked as the highest global cause of years lived with disability [2]. This highlights the high prevalence of LBP worldwide, and may also reflect the difficulty of successful LBP management. In primary care, approximately 85% of patients with LBP have no specific underlying causes or pathology [3]. Patients with non-specific LBP often experience recurrent pain, and the majority of these patients suffer from chronic pain [4–5]. Recurrent and chronic LBP may result in a serious social and economic burden.

Psychological factors have been widely acknowledged as contributors to the chronicity of LBP [6–7]. These factors include pain catastrophizing, fear-avoidance beliefs, and psychological distress. A number of previous reports suggested an association between psychological factors and poor long-term outcomes [5, 8–9]. In primary care, cognitive behavioral therapy focused on psychological factors is a dominant treatment approach for people with LBP [5]. To provide efficient, targeted care, it is becoming common to stratify patients with LBP according to their risk for poor long-term outcomes [10]. Significant clinical benefits and cost-effectiveness of stratified care compared with non-stratified physiotherapy practice have been demonstrated in a randomized clinical trial [11].

The STarT Back Tool (STarT) has been widely used to stratify patients with LBP according to risk for chronicity (Fig 1). The STarT was originally developed as a screening tool for prognostic indicators of back pain to help primary care clinical decision-making in the UK [12]. The STarT consists of 9 items. Items 1–4 evaluate physical factors, and items 5–9 assess psychosocial factors. The STarT classifies patients into three risk groups: patients with a total score of 0–3 are classified as low-risk; patients with a total score of $\geq$ 4 but a psychosocial subscore of $\leq$ 3 as medium-risk; and patients with a psychosocial subscore of $\geq$ 4 are classified as high-risk [12] (Fig 2). Targeted treatments have been developed for patients in each risk group: a minimal intervention by general practitioners or physiotherapists for the low-risk group, physiotherapy to address pain and disability for the medium-risk group, and psychologically-informed physiotherapy to address pain and disability as well as psychosocial obstacles to recovery for the high-risk group [11, 13, 14].

Although the STarT has been translated into various languages, no validated Japanese version was available. In our previous study, we translated the original English version of the STarT into Japanese (STarT-J) and linguistically validated it [15]. As a next step, we conducted online surveys with Japanese people with LBP to evaluate the psychometric properties of the STarT-J. The present analysis aimed to evaluate the reliability and validity of the STarT-J in a large number of Japanese people with LBP, using cross-sectional data from these surveys.

The Keele STarT Back Screening Tool

Patient name: _______________________________ Date: _____________

Thinking about the **last 2 weeks** tick your response to the following questions:

		Disagree 0	**Agree** 1
1	My back pain has **spread down my leg(s)** at some time in the last 2 weeks	☐	☐
2	I have had pain in the **shoulder** or **neck** at some time in the last 2 weeks	☐	☐
3	I have only **walked short distances** because of my back pain	☐	☐
4	In the last 2 weeks, I have **dressed more slowly** than usual because of back pain	☐	☐
5	It's not really safe for a person with a condition like mine to be physically active	☐	☐
6	**Worrying thoughts** have been going through my mind a lot of the time	☐	☐
7	I feel that **my back pain is terrible** and **it's never going to get any better**	☐	☐
8	In general I have **not enjoyed** all the things I used to enjoy	☐	☐

9. Overall, how **bothersome** has your back pain been in the **last 2 weeks**?

Not at all	Slightly	Moderately	Very much	Extremely
☐	☐	☐	☐	☐
0	0	0	1	1

Total score (all 9): __________________ **Sub Score (Q5-9):**______________

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Fig 1. STarT Back Tool. Response options for items 1–8 are "disagree" (0 points) or "agree" (1 point). Responses to item 9 are on a scale of 1–5: "not at all," "slightly," "moderately," "very much," or "extremely." The first three options ("not at all," "slightly," and "moderately") are scored as 0, and the remaining two options ("very much" and "extremely") are scored as 1. Items 1–4 constitute the physical subscale. Items 5–9 constitute the psychosocial subscale.

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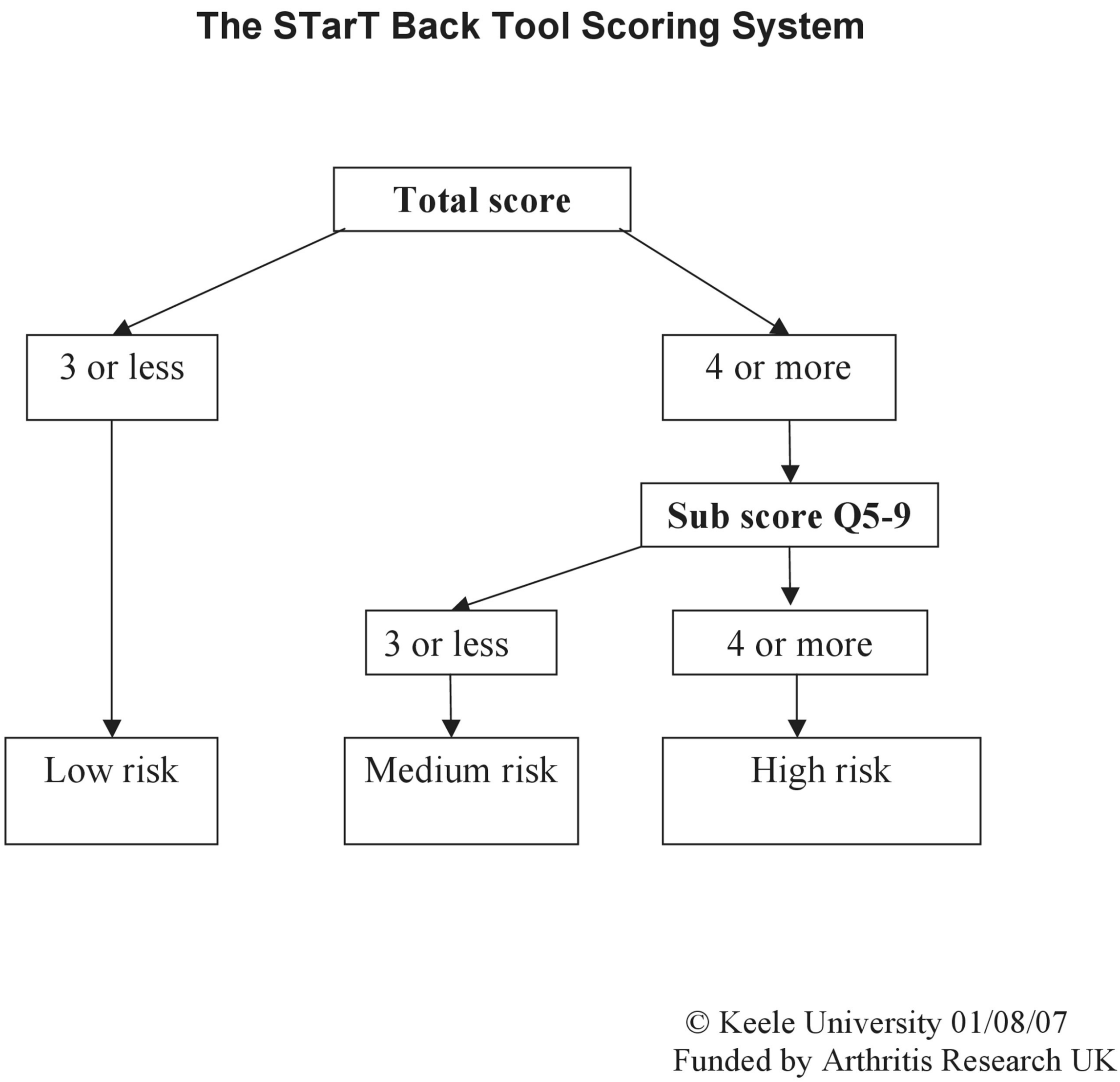

Fig 2. STarT Back Tool risk stratification. Sub score Q5–9: psychosocial subscale.

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Materials and Methods

Study population

To assess the psychometric properties of the STarT-J, we conducted online surveys collecting information on LBP in the Japanese population in January and February, 2014. Participants were recruited from an online panel provided by an Internet research company, UNITED, Inc. (Tokyo, Japan), which included approximately 1.25 million individuals aged 20–64 years registered as research volunteers. From these volunteers, 965,919 individuals were randomly selected and invited by e-mail to complete an online questionnaire on health problems associated with pain (first survey). We obtained 52,842 responses by the end of January 2014. Of these initial respondents, those who had LBP in the last 4 weeks were invited to complete another online questionnaire (secondary survey). LBP was defined as pain in the lower back experienced in the last 4 weeks that lasted for more than 1 day, according to the standard definition of LBP proposed by Dionne et al. [16]. Pain associated with menstruation or pregnancy and pain during a feverish illness were excluded. A diagram showing the lower back area (between the inferior costal margin and gluteal folds) was provided in the questionnaire. The secondary survey closed on 7 February 2014, when the total number of responses reached 2000. The mean (standard deviation [SD]) age of respondents in the secondary survey was 47.7 (9.3) years and 54.1% were male. We conducted two subsequent surveys, 6 and 24 weeks after the secondary survey, to follow up respondents and investigate their LBP condition. In the present analysis, we analyzed secondary survey data to evaluate the psychometric properties of the STarT-J.

We obtained approval from the Medical/Ethics Review Board of the Japan Labour Health and Welfare Organization, Kanto Rosai Hospital (Approval number: 2012–22). Participation was voluntary, and no personal information was collected. Although no written informed consent was obtained, submitting a completed questionnaire was considered as evidence of consent. Potential participants first read an explanation of the aim of the survey and only those who agreed to participate could proceed to the questionnaire. As an incentive, participants received reward points for online shopping from the Internet research company.

Development of the linguistically-validated STarT-J

In our previous study [15], the STarT was translated into Japanese and linguistically validated in a general cross-cultural adaptation process [17–19]. This process occurred in three steps: (1) forward-translation (English to Japanese), (2) back-translation (Japanese to English), and (3) cognitive debriefing. In the third step, we conducted a pilot study to assess if the questions and response scales were understandable and correctly interpreted by Japanese patients. After considering their feedback, and consultation with a specialist as necessary, we published the STarT-J [15].

Measures

We included a number of measures in the online questionnaires.

Pain. The degree of pain associated with LBP during the last 4 weeks was assessed by a numerical rating scale (NRS), ranging from 0 (no pain at all) to 10 (the worst pain imaginable).

Disability caused by LBP. We used the Roland—Morris Disability Questionnaire (RDQ) to assess the LBP-related disability participants experienced in their daily lives. The RDQ comprises 24 Yes/No questions. The total score ranges from 0 to 24, with a higher score indicating greater disability. In this study, we used the Japanese version of the RDQ, for which the reliability and validity have been previously confirmed [20].

Fear-avoidance beliefs. Fear of pain can lead to avoidance of physical activity, an important indicator of a poor long-term LBP prognosis. The Fear-Avoidance Belief Questionnaire (FABQ), consisting of physical activity and work subscales, is widely used to assess fear-avoidance beliefs [21]. We used the FABQ physical activity subscale (FABQ-PA). The FABQ-PA score ranges from 0 to 30; a higher score indicates a stronger fear-avoidance belief. We also used the Tampa Scale of Kinesiophobia (TSK) [22–23], originally developed to measure the fear of movement or injury. The total TSK score sums the scores of 17 items (each rated on a scale of 1–4), and ranges from 17 to 68. A higher score indicates a higher level of kinesiophobia.

Catastrophizing. Pain catastrophizing is also an important indicator of poor LBP prognosis. Catastrophizing was assessed using the Pain Catastrophizing Scale (PCS), originally developed to measure negative attitudes toward pain involving rumination, helplessness, and magnification. The PCS consists of 13 items. The total score ranges from 0 (no catastrophizing) to 52 (greater catastrophizing). We used the Japanese version of the PCS, for which the reliability and validity have been previously confirmed [24].

Depression and anxiety. A 14-item self-assessment scale, the Hospital Anxiety and Depression Scale (HADS), was used to measure anxiety and depression. The HADS comprises anxiety and depression subscales, each with seven items. The total score ranges from 0 to 21, with a higher score indicating more mental distress. The validity and reliability of the Japanese version of the HADS have been previously confirmed [25].

General health status. The EuroQol 5 Dimension (EQ-5D) [26] is an instrument that provides a simple, descriptive profile and single index value for general health status. The index score is derived from conversion of all responses, and ranges from −0.11 to 1.00. A score of 1 means "perfect health" and a score of 0 denotes "death."

Somatic symptoms. Somatization was assessed using the 7-item somatization subscale from the Brief Symptom Inventory (BSI) [27]. Seven symptoms (faintness or dizziness, pains in the heart or chest, nausea or upset stomach, trouble getting your breath, numbness or tingling in parts of the body, feeling weak in parts of the body, hot or cold spells) are rated on a 5-point scale: "not at all," "a little bit," "moderately," "quite a bit," and "extremely." We used the linguistically validated Japanese version of the BSI-somatization subscale [28].

Data analyses

Participants' demographic and clinical characteristics were summarized using descriptive statistics. To examine floor and ceiling effects, percentages of respondents with total scores of 0 and 9 were calculated. Floor and ceiling effects were considered to exist when more than 15% of respondents had the lowest or highest possible score [29]. To examine the reliability of the STarT-J, we evaluated internal consistency by calculating Cronbach's alpha coefficients for the overall scale and the psychosocial subscale. An alpha index more than 0.70 is considered to indicate satisfactory internal consistency [30].

Concurrent validity was evaluated by measuring correlations between the previously described reference instruments and the STarT-J total score and psychosocial subscore using Spearman's correlation coefficients. Correlation coefficients were evaluated according to the criteria for correlation strength in psychometric validation proposed by Cohen: 0.10 representing a weak, 0.30 a moderate, and 0.50 a strong correlation [31].

To assess discriminant validity, we calculated the area under the curves (AUCs) for the total scores and psychosocial subscores against the reference standards. We defined cases using the following cut-off values: a RDQ score of ≥ 7 for disability, a PCS score of ≥ 20 for catastrophizing, a TSK score of ≥ 41 for fear-avoidance beliefs, and a HADS score of ≥ 8 for depression and anxiety. In addition, a single question was used to determine the presence of referred leg pain within the last 4 weeks. Discriminative ability was interpreted according to the same criteria as used in the original STarT study: 0.70 to < 0.80 indicating acceptable discrimination, 0.80 to < 0.90 indicating excellent discrimination, and ≥ 0.90 indicating outstanding discrimination [12].

For known-groups validity, to test whether the STarT-J scores differentiated participants with known differences, we examined 1) total scores among the groups with a different number of somatic symptoms, and 2) the number of absences due to LBP among the three risk groups (low, medium, and high) using the Jonckheere—Terpstra test. If participants responded "moderately," "quite a bit," or "extremely" to a BSI item, they were considered to have that somatic symptom. Participants were then categorized into three groups according to the number of somatic symptoms: no symptoms, one symptom, and two or more symptoms. With respect to the number of absences, days on which participants could not perform housework were counted, as well as absences from work. It was hypothesized that participants with more somatic symptoms would have higher total scores, and that participants in the high-risk group would have experienced more LBP-related absences.

All statistical analyses were performed using SAS version 9.3 (SAS Institute, Cary, NC, USA). The level of significance was set at 0.05.

Results

Participant characteristics

The present analysis included data for 2000 Japanese patients with LBP. Table 1 presents a summary of participants' demographic and clinical characteristics. The mean (SD) age was 47.7 (9.3) years; 54.1% of participants were male. More than half (53.7%) of the participants had experienced LBP for more than 1 year. Most participants (92%) experienced recurrent LBP, and more than half (52.9%) reported having LBP 10 times or more.

Scores of the measures

The mean (SD) score for the STarT-J was 2.2 (2.1). No remarkable ceiling effect was observed as 0.9% of participants had the highest score of 9. However, a floor effect was observed as 23.4% of participants had the lowest score of 0. The score distribution for each item is shown in Table 2. Participants were classified into three risk groups according to their STarT-J score: 1557 (77.9%) into the low-risk group, 294 (14.7%) into the medium-risk group, and 149 (7.5%) into the high-risk group.

Reliability

The Cronbach's alpha coefficients were 0.75 for the overall scale and 0.66 for the psychosocial subscale.

Concurrent validity

To examine concurrent validity, Spearman's correlation coefficients were used to measure correlations between the STarT-J total score/psychosocial subscore and the pain NRS, RDQ, FABQ-PA, TSK, PCS, HADS, and the EQ-5D (Table 3). The correlation coefficients for the total score ranged from 0.30 (HADS depression) to 0.59 (RDQ), demonstrating a moderate to strong correlation with these reference standards. Similarly, correlation coefficients for the psychosocial subscore ranged from 0.33 (FABQ-PA) to 0.54 (RDQ), demonstrating a moderate to strong correlation. Both the total score and psychosocial subscore were strongly negatively correlated with the EQ-5D ($\gamma = -0.56$ and $\gamma = -0.53$, $p < 0.0001$). In terms of the correlation with psychosocial measures, the total score was moderately correlated with the TSK ($\gamma = 0.49$), whereas the psychosocial subscore was strongly correlated ($\gamma = 0.53$). Moderate correlation coefficients were observed for both the total score and psychosocial subscore with the PCS ($\gamma = 0.46$ and $\gamma = 0.49$) and the HADS ($\gamma = 0.40$ and $\gamma = 0.45$) ($p < 0.0001$ for all).

Discriminant validity

To assess discriminant validity, AUCs were calculated for the total score and psychosocial subscore against the cases defined by the reference standards (Table 4). The AUCs for the total score were all above 0.70, indicating acceptable to excellent discriminative ability, with the exception of depression and anxiety (0.65). For the psychosocial subscore, the AUCs ranged

Table 1. Participant characteristics: psychometric testing of the STarT-J (n = 2000).

Characteristics	n (%)	Mean (SD)
Sex		
Male	1081 (54.1)	
Female	919 (46.0)	
Age (years)		47.7 (9.3)
BMI $\geq$ 25 (kg/m^2)	506 (25.3)	
Duration of low back pain		
< 2 weeks	350 (17.5)	
$\geq$ 2 weeks, < 1 month	188 (9.4)	
$\geq$ 1, < 3 months	184 (9.2)	
$\geq$ 3, < 6 months	90 (4.5)	
$\geq$ 6 months, < 1 year	115 (5.8)	
$\geq$ 1, < 3 years	200 (10.0)	
$\geq$ 3 years	873 (43.7)	
Number of recurrence		
1	160 (8.0)	
2	135 (6.8)	
3–4	340 (17.0)	
5–9	308 (15.4)	
$\geq$10	1057 (52.9)	
STarT-J score		2.2 (2.1)
RDQ score		4.2 (4.7)
FABQ-PA score		12.9 (4.7)
TSK score		41.0 (6.5)
PCS total score		21.6 (10.0)
PCS rumination		10.6 (4.3)
PCS helplessness		6.2 (4.2)
PCS magnification		4.7 (2.7)
HADS total score		17.2 (6.7)
HADS anxiety		8.7 (3.4)
HADS depression		8.5 (4.1)
EQ-5D index score		0.78 (0.16)
NRS for low back pain		4.2 (1.8)

Values are n (%), or mean (SD).
STarT-J, the Japanese version of the STarT Back Tool; BMI, body mass index; RDQ, Roland—Morris Disability Questionnaire; FABQ-PA, Fear-Avoidance Belief Questionnaire Physical Activity Subscale; TSK, Tampa Scale for Kinesiophobia; PCS, Pain Catastrophizing Scale; HADS, Hospital Anxiety and Depression Scale; EQ-5D, EuroQol 5 Dimension; NRS, numerical rating scale.

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from 0.67 (depression and anxiety) to 0.79 (disability), indicating poor to acceptable discriminative ability.

Known-groups validity

We examined the STarT-J total scores and risk groups among participants with known-differences. As hypothesized, participants with more somatic symptoms had higher total scores. The mean (SD) score of participants with no somatic symptoms was 1.71 (1.76), one somatic symptom was 2.73 (2.14), and two or more somatic symptoms was 3.76 (2.50) (Fig 3). A linear

Table 2. Score distribution of STarT-J items and risk group distribution (n = 2000).

Item	Number of participants who answered "agree" (1 point) n (%)
1	442 (22.1)
2	1069 (53.5)
3	317 (15.9)
4	264 (13.2)
5	574 (28.7)
6	652 (32.6)
7	425 (21.3)
8	351 (17.6)
9	239 (12.0)
Risk group distribution	
Low-risk	1557 (77.9)
Medium-risk	294 (14.7)
High-risk	149 (7.5)

Values are n (%).

STarT-J: The Japanese version of the STarT Back Tool. For item 9, answers of "very much" and "extremely" were scored as 1 point, and were counted as "agree"; the answers "not at all," "slightly," and "moderately" were scored as 0 points, and were not included.

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increasing trend in total score across groups with an increasing number of somatic symptoms was observed (Jonckheere-Terpstra test, $p < 0.0001$). With respect to the associations between risk groups and the number of absences, participants in the high-risk group reported a larger number of absences (Fig 4). The mean (SD) LBP-related absences in the low-risk group was 4.0 (5.4) days, 6.6 (8.3) days in the medium-risk group, and 12.6 (11.1) days in the high-risk group. A linear increasing trend in the number of absences across the risk groups was observed (Jonckheere-Terpstra test, $p < 0.0001$).

Table 3. Spearman's correlation coefficients for the STarT-J and related measures.

Measures	Total score Coefficients (95% CI)	Psychosocial subscore Coefficients (95% CI)
RDQ	0.59 (0.56–0.62)	0.54 (0.51–0.57)
FABQ-PA	0.34 (0.30–0.37)	0.33 (0.29–0.37)
TSK	0.49 (0.45–0.52)	0.53 (0.50–0.56)
PCS total	0.46 (0.42–0.49)	0.49 (0.46–0.52)
PCS rumination	0.43 (0.40–0.47)	0.44 (0.41–0.48)
PCS helplessness	0.39 (0.35–0.43)	0.43 (0.39–0.46)
PCS magnification	0.40 (0.36–0.44)	0.43 (0.39–0.47)
HADS total	0.40 (0.36–0.44)	0.45 (0.41–0.48)
HADS anxiety	0.42 (0.38–0.46)	0.46 (0.42–0.49)
HADS depression	0.30 (0.26–0.34)	0.35 (0.31–0.39)
EQ-5D	–0.56 (–0.59 ––0.52)	–0.53 (–0.56 ––0.50)
NRS for low back pain	0.42 (0.38–0.46)	0.39 (0.35–0.42)

Note: p < 0.0001 for all correlation coefficients. STarT-J, the Japanese version of the STarT Back Tool; CI, confidence interval; RDQ, Roland—Morris Disability Questionnaire; FABQ-PA, Fear-Avoidance Belief Questionnaire Physical Activity Subscale; TSK, Tampa Scale for Kinesiophobia; PCS, Pain Catastrophizing Scale; HADS, Hospital Anxiety and Depression Scale; EQ-5D, EuroQol 5 Dimension; NRS, numerical rating scale.

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Table 4. AUCs for STarT-J total score and psychosocial subscore against reference standards.

Reference standards	Case definition	Total score AUC (95% CI)	Psychosocial subscore AUC (95% CI)
Disability	RDQ score ≥ 7	0.83 (0.81–0.85)	0.79 (0.77–0.82)
Referred leg pain	Yes	0.76 (0.73–0.79)	0.68 (0.65–0.72)
Fear-avoidance belief	PCS score ≥ 20	0.71 (0.69–0.73)	0.72 (0.70–0.74)
Catastrophizing	TSK score ≥ 41	0.74 (0.72–0.76)	0.75 (0.73–0.77)
Depression and anxiety	HADS score ≥ 8	0.65 (0.63–0.68)	0.67 (0.65–0.69)

AUC, area under the curve; STarT-J, the Japanese version of the STarT Back Tool; CI, confidence interval; RDQ, Roland—Morris Disability Questionnaire; PCS, Pain Catastrophizing Scale; TSK, Tampa Scale for Kinesiophobia; HADS, Hospital Anxiety and Depression Scale.

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Discussion

In this analysis, we evaluated the psychometric properties of the STarT-J. In summary, the overall scale of the STarT-J was internally consistent, and the STarT-J had acceptable concurrent validity, discriminant validity, and known-groups validity in Japanese patients with LBP.

The Cronbach's alpha coefficient for the overall scale (0.75) demonstrated sufficient internal consistency, and was similar to the original and other language versions: 0.79 for the original [12], 0.74 for the French [32], 0.74 for the Brazilian Portuguese [33], 0.82 for the Iranian [34], and 0.83 for the Persian [35] versions. Although these results could not be compared directly because the study methods varied, the similar values support that the overall scale of the STarT-J is internally consistent and no items are redundant. The Cronbach's alpha coefficient for the psychosocial subscale was 0.66, below the value of 0.70 considered necessary to claim

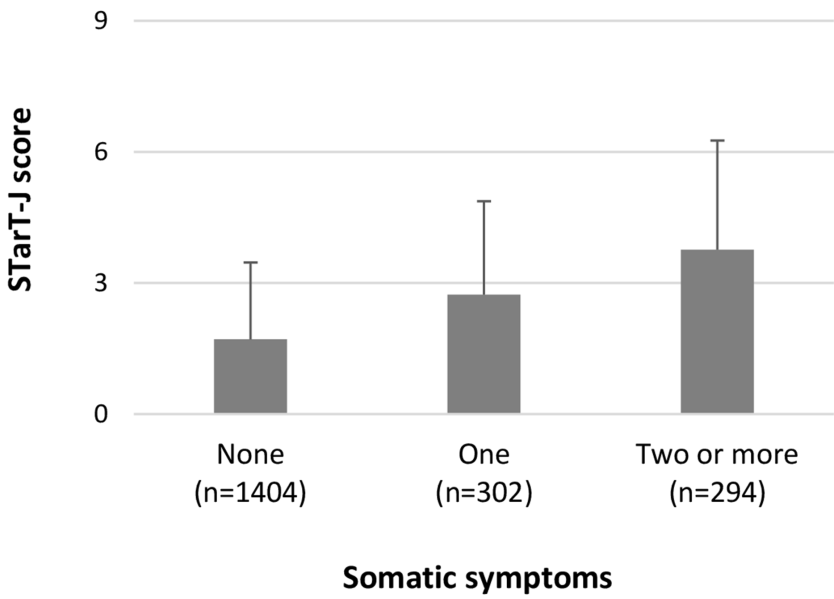

Fig 3. Mean STarT-J scores for participants with different numbers of somatic symptoms. The linear trend was tested using the Jonckheere-Terpstra test (p < 0.0001). STarT-J: The Japanese version of the STarT Back Tool. Number of somatic symptoms was assessed by the Brief Symptom Inventory somatization scale: a response of "moderately," "quite a bit," or "extremely" to an item was interpreted as the presence of that somatic symptom, and thus counted.

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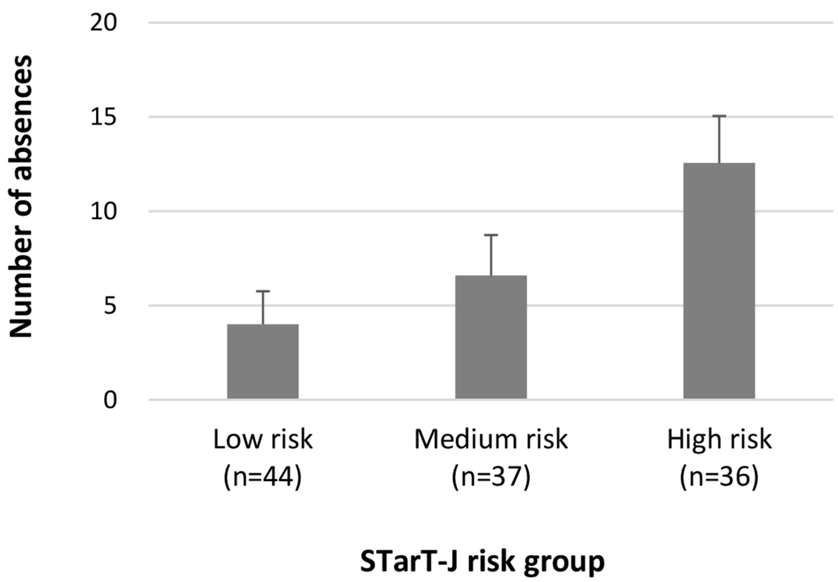

Fig 4. Mean number of absences for the three STarT-J risk groups. The linear trend was tested using the Jonckheere-Terpstra test ($p < 0.0001$). STarT-J: The Japanese version of the STarT Back Tool.

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the subscale is internally consistent. However, it should be taken into consideration that the coefficient for the subscale was also lower than for the overall scale in the original version, although it was still 0.74 [12].

To assess concurrent validity, we analyzed the correlations between the STarT-J and reference standards (the pain NRS, RDQ, FABQ-PA, TSK, PCS, HADS, and EQ-5D). Overall, the Spearman's correlation coefficients indicated that both the total score and the psychosocial subscore were moderately to strongly correlated with these existing scales. In particular, the STarT-J total score was strongly correlated with the RDQ ($\gamma = 0.59$). Similar results were observed in the German ($\gamma = 0.55$) [36], French ($\gamma = 0.74$) [32], and Persian ($\gamma = 0.811$) [35] versions. Although a direct comparison cannot easily be made, these similar results reinforce the concurrent validity of the STarT-J.

Discriminant validity was assessed by calculating the AUCs for the total score and the psychosocial subscore. For the total score, the AUCs for disability and referred leg pain were both higher than the AUCs for fear-avoidance beliefs, catastrophizing, and depression and anxiety. This demonstrated that the total score better discriminated cases defined by physical reference standards. However, for the psychosocial subscore, the AUCs for fear-avoidance beliefs, catastrophizing, and depression and anxiety were not remarkably higher than AUCs for the physical reference cases. These AUCs for the psychosocial reference cases were similar to those for the total score, indicating the psychosocial subscale might discriminate cases defined by the psychosocial reference standards at a similar level to the overall scale. A similar trend was observed in the original STarT [12], although overall, the AUCs were higher compared with the STarT-J.

To assess known-groups validity, we investigated relationships between total scores and the number of somatic symptoms, and between risk groups and the number of absences. Participants with more somatic symptoms had higher total scores, and those in the high-risk group had experienced greater LBP-related disability. This demonstrated that the STarT-J can differentiate patients with different levels of LBP-related problems.

The present study has some limitations. First, we did not examine the test—retest reliability. The intra-class, test—retest reliability over specific time intervals should therefore be evaluated in a future study. Second, the analysis might have included patients not targeted by the STarT, that is, patients who had specific causes of LBP. The diagnostic triage for LBP is to classify LBP into one of three categories: LBP with specific pathologic change ("red flag"), LBP with sciatica/radicular syndrome, or non-specific LBP [37]. According to this classification, six of the participants in the present analysis were probable "red flags," 308 had radicular syndrome, and the remaining 1686 participants were considered to have non-specific LBP. As the original study included patients with non-specific LBP who had referred leg pain [12], the STarT is considered applicable to patients with LBP potentially associated with sciatica/radicular syndrome. Therefore, assuming diagnoses were accurate, most participants probably fit into the STarT target group. However, it should be noted that these diagnoses might not necessarily be accurate as they were based on participants' self-report. Third, the study population might not be consistent with the primary care population. Our study included more low-risk participants and less high-risk participants compared with the original study [12]. This might be because we recruited from a general Japanese population registered with an online panel rather than from patients in hospitals. Our study population would therefore represent the general Japanese population with LBP. As the observed floor effect suggests, more patients might have LBP that was not sufficiently severe to require hospital care. Although our study population was broader than the primary care population, the percentage of patients with non-specific LBP was similar to that observed in primary care settings. In our study, 1686 participants (84.3%) probably had non-specific LBP. In primary care, approximately 85% of patients with LBP have non-specific LBP [3]. Therefore, our study population resembled the primary care population in terms of the distribution of non-specific LBP. Fourth, as this was a cross-sectional study, it did not assess the ability of the STarT-J to predict chronicity of LBP. To assess its predictive ability, longitudinal studies will be necessary to investigate associations between risk groups and long-term outcomes of patients with LBP.

In the present analysis, we evaluated the psychometric properties of the STarT-J to enable Japanese clinicians to use the scale in the early stages of LBP. The STarT is a simple and quick tool, and is suitable for use in primary care settings. Stratified care is a dominant approach in the management of LBP [10]. Stratified care based on the STarT risk groups has been shown to be clinically and economically beneficial for patients with LBP [11, 38]. Therefore, we expect that the STarT-J may facilitate early stratified care in primary care settings in Japan. This may alleviate the physical, social, and economical burden of LBP in the Japanese population.

In conclusion, acceptable internal consistency for the overall STarT-J scale demonstrated the reliability of the STarT-J in Japanese patients with LBP; acceptable concurrent validity, discriminant validity, and known-groups validity demonstrated the validity. In a subsequent analysis, the ability of the STarT-J to predict chronicity of LBP will be examined using longitudinal data, to validate its clinical use in Japanese patients.

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Author Contributions

Conceived and designed the experiments: KM HO ST. Performed the experiments: KM HO. Analyzed the data: KM HO NK YH TS ST. Contributed reagents/materials/analysis tools: KM HO. Wrote the paper: KM HO NK YH TS ST.

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Original

The Current State along with Outstanding Issues Related to Email-Based Guidance by Physical Therapists Aiming to Prevent Low Back Pain among Workers

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Abstract

Low back pain (LBP) is more likely than any other symptom to prevent people from working, making the establishment of measures to prevent and reduce LBP vital in the workplace. In our previous study, we have conducted Physical Consultant research (PCo research) in order to verify the effect of email-based guidance provided by currently working physical therapists (the advisors) to workers (the clients) in preventing LBP. We found a significant improvement of Work Ability Index and Fear-Avoidance Beliefs Questionnaire among the clients in the PCo research. The purpose of this study was to consider means of improving the effectiveness of email-based guidance using computers and mobile terminals. The method involved the use of a PCo research database, with the results of the questionnaire survey carried out among advisors and clients analyzed once the study was completed. The results revealed that one advisor can receive and respond to questions from five clients at any one time. Questions from the clients included not only those related to LBP prevention, but also some related to other musculoskeletal symptoms, general lifestyle, and care for family members. We thought that the physical therapists are the profession most likely to be able to respond to such questions. The development of a dedicated system will be required in order to manage data from multiple clients and implement efficient and effective email-based guidance.

(JJOMT, 64: 113—118, 2016)

—Key words—
Physical therapist, Low back pain, Occupational health

Introduction

In Japan, from April 2008, medical insurers have been required to execute specific health examinations and offer specific health guidance (Specified Health Examinations and Guidance) focusing on visceral fat accumulation[1]. The subjects from 40 years old to 74 years old are categorized based on the results of examinations and questionnaires, according to their level of risk, into those requiring "motivational support" and those requiring "proactive support", with Specified Health Guidance provided depending on these categorizations. "Proactive support" is provided among individual in one format from interview, telephone, letters and electronic communication (fax and email, etc.), or as a combination of these.

In the field of research into physical activities, measures offering support for physical activity have also been provided by the use of mobile phone messaging[2]. Furthermore, trials using emails have begun in walking programs in occupational health[3]. We have already noted the short-term effects of guidance and support in improving physical activity when provided by mobile telephone message to healthy young people, and provided by an electronic communication including mobile telephone message to healthy elderly people[4)5)]. Yamatsu, et al. reported that the short-term success rate of intervention in physical activity using the internet and mobile phone terminals is at least 50%[6)]. However, the long-term benefits of intervention in physical activity using the internet and mobile terminal devices are unclear, and the study of its long-term impact, including the development of a methodology for effective intervention, is an issue for the future. While the long-term effects of intervention are still an issue for future consideration, it is considered to be an "effective tool for promoting changes in peoples' behavior"-which is also part of the current Specified Health Guidance.

In Japan, it has been found that 60% of workplace-related illnesses are due to low back pain (LBP)[7)], of which 85% is in the form of Non-Specific LBP (NSLBP), with no specific cause[8)9)]. It has also recently been clarified that psychological and social factors also contribute to NSLBP and that the provision of correct information and an encouraging attitude among those around the subject can contribute to relief from LBP[10)]. In terms of preventing LBP, the effect of guidance using electronic communication was not examined. In our previous study, we conducted a Physical Consultant research (PCo research) in order to verify the effects of email-based guidance provided by physical therapists (the advisors) to workers (the clients) in preventing LBP among workers who had in the past suffered from NSLBP[11)].

In the present study, we used a database of PCo research and analyzed the results of a questionnaire conducted among advisors and clients once intervention had ended, in order to consider a more effective means of email-based guidance using computers and mobile terminal devices.

Methods

Definition of PCo research

This research project was conducted between June 2013 and February 2014, with the aim of verifying the effectiveness of email-based guidance aiming to prevent LBP among worker, and from this, propose a new business model for the utilization of physical therapists in the field of occupational health[11)]. Fig. 1 shows a flow chart of the PCo research. The project allocated 20 currently working advisors with a minimum of three years' of clinical experience to 20 clients, for the purpose of the advisors providing individual guidance on how to prevent LBP by email. Two of the physical therapists who had experience providing advice regarding the prevention of LBP in worker, compiled a basic concept[12)] for the prevention of LBP, with consultations and the content of guidance stored and shared via the cloud computing network at the research secretariat. The email-based guidance intervention was conducted for six months, during which time advisors sent a minimum of eight emails to clients. Moreover, in addition to the regular emails from advisors, the advisors also responded to queries from their clients.

The results of PCo research showed a significant increase in the Work Ability Index (WAI)[13)] which is used to express how skillfully each client is engaging in his/her tasks, along with a tendency towards improvement within the Fear-Avoidance Beliefs Questionnaire (FABQ)[14)] which expresses the subject's state of mind in regard to avoiding the fear of LBP, subsequent to the email-based guidance. In the present study, the Helsinki Declaration was fully adhered to in the use of the PCo research database and no individuals were identified.

Details of the questionnaire

The questionnaire was conducted after completion of the email-based guidance intervention. Questions asked to advisors included: "1) Did you need personal information about the client? (Y/N)"; "2) Number of days taken for the advisor to respond to a question from the client (No. of days)"; "3) Time spent on forming a response by the advisor to a question from a client (No. of minutes)"; "4) Number of responses by email by client to advisor (No. of responses)"; "5) Ideal amount of time spent by advisor in order to come up with a response to a question from a client (from the advisor's perspective) (No. of minutes)"; "6) Details of questions not related to LBP"; "7) No. of clients it would be possible to respond to in one month (No. of responses)"; and "8) Problems with the PCo research (from the advisor's perspective)". Questions 6) and 8) required a free response.

Questions asked to clients included: "1) Do you think that the advice provided by your advisor in emails was helpful in preventing LBP? (Y/N)"; and "2) Would you like to use email-based guidance again? (Y/N)".

The physical therapists dispatched by the research secretariat implemented a lecture for 90 minutes in regard to the prevention of low back pain for company employees. At this time, an explanation of the Physical Consultant research (PCo research) was provided orally, with those giving consent appointed as subjects (clients).

↓

Clients who gave their consent were allocated to a responsible physical therapist (advisor), in regard to whom, the clients' personal information was not disclosed. Personal information about the advisors was also not provided to the clients.

↓

Outline of Email-based guidance

Period	**No. of times***	**Advisor**	**Client**
Start	1st time	Advisor sends email to client, providing guidance based on questions submitted by client.	Receives email from advisor, and sends questions to advisor.
Two weeks	2nd time		
First month	3rd time		
Second month	4th time		
Third month	5th time		
Fourth month	6th time		
Fifth month	7th time		
Sixth month	8th time		

↓ ↓

Survey on completion*1
Research secretariat implements questionnaire survey in regard to advisors in order to analyze issues related to the email-based guidance.

Survey on completion*2
Research secretariat implements questionnaire survey in regard to clients, in order to ascertain effectiveness of email-based guidance.

Fig. 1 Physical Consultant Research Flow Chart

Advisors: Physical therapists, Clients: Worker, Research secretariat: the Japanese Study Group of Physical Therapy in Occupational Health.

No. of times*: Basic number of times emails sent to clients by advisors. If the client asks questions, the number of times emails and responses are sent may increase based on the details of the advice sought and provided.

Survey on completion*: Data from both surveys on completion (1 and 2) implemented in regard to advisors and clients was utilized in this study.

Questions 3) and 5) for the advisors were compared using the Mann-Whitney U-test. The statistical software used was IBM SPSS Statistics ver. 19, with statistical significance defined at 5%.

Results

The results of the questionnaire survey conducted in regard to advisors are shown in Table 1. Since questions 6) and 8) required a free response, similar responses were compiled and the record shows responses in the order of popularity. No significant difference was between "Time spent on forming a response by the advisor to a question from a client" and "Ideal amount of time spent by advisor in order to come up with a response to a question from a client" (questions 3) and 5)).

The results of the questionnaire survey conducted in regard to clients revealed that 88% responded "Yes (it was helpful)" to the question "Do you think that the advice provided by your advisor in emails was helpful in preventing LBP?", and 76% responded "Yes (would like to use again)" in response to the question "Would you like to use email-based guidance again?"

Table 1 Results of Questionnaires given to Advisors

	Question	Response
1	Need for personal information about the client	All advisors required personal information from their clients
2	Time taken for the advisor to respond to a question from the client	2.0 ± 0.4 days
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4	No. of responses by email by client to advisor	4.7 ± 4.2 times
5	Ideal amount of time spent by advisor in order to come up with a response to a question from a client	20.3 ± 13.7 min.
6	Questions related to topics other than low back pain	Stiff or painful shoulders: n = 2 Chills: n = 1 Stiffness upon waking in the morning: n = 1 Care for family members: n = 1 Obesity: n = 1 Lack of exercise: n = 1 Lower extremity pain: n = 1
7	No. of clients it would be possible to respond to in one month (from the advisor's perspective)	5.3 ± 7.4 people
8	Problems with the PCo research (from the advisor's perspective)	Need subject's information in advance: n = 4 Not clear whether or not client has seen email: n = 2 Need guidelines and examples for composing emails: n = 2 Need to decide how to follow-up if client does not respond: n = 2 Not clear if information being provided is what client requires: n = 1 Difficult to tell whether guidance is effective: n = 1 Differences in advice given by different advisors; this may cause dissatisfaction among clients: n = 1 Confused about what to do when clients do not respond: n = 1 Difficult to build trust with client due to anonymity: n = 1 Need for quantitative data and tools that allow for shared awareness between client and advisor: n = 1

Discussion

In the present study, we used a database of information from past PCo research and analyzed the results of a questionnaire conducted among advisors and clients once intervention had ended, in order to consider a more effective means of email-based guidance using computers and mobile terminal devices.

In the PCo research, we took care to ensure that the advisors could not identify the clients and that the clients could not identify the advisors even after the study ended. The results of the questionnaire implemented on advisors showed that all advisors stated they required personal information from clients in order to provide email-based guidance. In the field of physical activity research it has been reported that the greater the relevancy of messages sent to subjects in support of physical activities, the more likely it is that the message will be received and acted upon[15]. Obtaining personal information about the client is considered to facilitate the provision of guidance that is more relevant to factors in the client's background. As such, disclosure of personal information is an issue that requires more consideration. During the PCo research, a unified concept of guidance to prevent LBP[10] was provided; however, if intervention is to be considered in indeterminate multiple cases, even if personal information is not available. It will be necessary to compile a manual for email-based guidance methods to ensure a smooth response. Guidance for prevention of LBP needs to include guidance related to physical activity and exercise, as well as provisions for psychological and social factors such as FAB[16]. When giving individual advice, it is easy to respond to individual psychological and social factors. However, when giving guidance to a group, it is more difficult to focus on individual psychological and social factors, and as such, is an issue that will require consideration in the future.

The results of the questionnaire survey showed that the average ideal amount of time required by advisors in order to come up with a response to a question from a client was 20.3 ± 13.7 minutes, while the time taken to respond was in fact 22.0 ± 9.7 minutes. There was no significant difference noted between the two, indicating that advisors were able to reply within their ideal time limit. When asked how many clients they could handle per month, the average response was diverse at 5.3 ± 7.4; however, it was believed that the group of currently active physical therapists in this study could manage email-based guidance with around 100 clients at any one time. Clients asked for advice on a diverse range of issues other than LBP, including other musculoskeletal symptoms, general lifestyle, and care for family members. It is thought that it would be difficult for people other than physical therapists, who have anatomical, physiological and other types of medical knowledge, as well as experience with rehabilitation, etc., to respond to medical and caregiving problems, to respond to these questions, and as such, there is a great need for physical therapists to act as advisors. The period of time taken for advisors to respond to clients was on average 2.0 ± 0.4 days, although confirmation of whether or not this was an acceptable period of time for clients was not carried out. Furthermore, advisors sent a minimum of eight emails to clients, with an average number of responses from clients of 4.7 ± 4.2, and it is not known whether the details of the emails sent were highly satisfactory or not. In a previous survey of 844 patients currently attending orthopedic clinics for treatment of chronic LBP, patients were asked to rank their "satisfaction with their current improvement in pain level" on a Rickert scale of 1 to 11; wherein, while the average response was 5.3, as many as 27% of respondents stated that they had "given up hope of any further relief" when asked "How much relief do you expect to gain from further treatment?"[17]. In this research, 88% of clients responded in the questionnaire that they felt the email-based guidance had been useful in preventing LBP, while 76% stated that they would like to receive further guidance. It should be noted in comparison that in prior research[17], although subjects were patients attending clinics, it is believed that this still represents a high level of satisfaction among clients with the email-based guidance.

In the future, in addition to considering the effectiveness of email-based guidance in research with regulated methodology, it is necessary to consider how to implement even more effective email-based guidance. The PCo research looked at 20 clients and the research secretariat was able to ascertain the content of emails between advisors and clients; however, when considering a response to a much larger number of clients, along with the development of advisors, it is believed that the development of a dedicated system will be required. Furthermore, cost/benefit analysis of email-based guidance must be carried out in order to acquire results that can demonstrate to corporations and clients the specific benefits of such a system.

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野村 卓生

腰痛予防を目的とした理学療法士によるメール指導の現状と課題

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—キーワード—
理学療法士，腰痛，産業保健

腰痛は，最も仕事に支障をきたしやすい疾患であり，いかに腰痛を予防し減らしていくかという職場での対策の確立が不可欠となっている．我々は以前に，労働者（以下，相談者）の腰痛予防を目的として理学療法士（以下，指導者）によるメール指導効果を検討するためにPhysical Consultant研究（以下，PCo研究）を実施した．PCo研究では，相談者の労働能力適応指標および腰痛恐怖回避思考の有意な改善を認めた．本研究の目的は，コンピューターや携帯端末機器を使用したメール指導に関して，より効果的な方法を検討することである．方法は，PCo研究のデータベースを用い，この研究で行われた指導者と相談者へのアンケート調査結果を分析することとした．結果，1人の指導者が同時期に5名の相談者の相談に対応可能なことが明らかとなった．相談者からは，腰痛予防に関連する内容だけではなく，他の筋骨格系の問題，生活習慣や家族の介護に関する相談があった．理学療法士は，これらの相談に対応できる最適な職種として考えられた．より多数の相談者および効果的なメール指導を行うにあたっては専用のシステム開発が必要と考えられた．

利益相反：利益相反基準に該当無し

（日職災医誌，64：113—118，2016）

Original

The Current State along with Outstanding Issues Related to Email-Based Guidance by Physical Therapists Aiming to Prevent Low Back Pain among Workers

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(Received: July 2, 2015)

Abstract

Low back pain (LBP) is more likely than any other symptom to prevent people from working, making the establishment of measures to prevent and reduce LBP vital in the workplace. In our previous study, we have conducted Physical Consultant research (PCo research) in order to verify the effect of email-based guidance provided by currently working physical therapists (the advisors) to workers (the clients) in preventing LBP. We found a significant improvement of Work Ability Index and Fear-Avoidance Beliefs Questionnaire among the clients in the PCo research. The purpose of this study was to consider means of improving the effectiveness of email-based guidance using computers and mobile terminals. The method involved the use of a PCo research database, with the results of the questionnaire survey carried out among advisors and clients analyzed once the study was completed. The results revealed that one advisor can receive and respond to questions from five clients at any one time. Questions from the clients included not only those related to LBP prevention, but also some related to other musculoskeletal symptoms, general lifestyle, and care for family members. We thought that the physical therapists are the profession most likely to be able to respond to such questions. The development of a dedicated system will be required in order to manage data from multiple clients and implement efficient and effective email-based guidance.

(JJOMT, 64: 113—118, 2016)

—Key words—
Physical therapist, Low back pain, Occupational health

Introduction

In Japan, from April 2008, medical insurers have been required to execute specific health examinations and offer specific health guidance (Specified Health Examinations and Guidance) focusing on visceral fat accumulation[1]. The subjects from 40 years old to 74 years old are categorized based on the results of examinations and questionnaires, according to their level of risk, into those requiring "motivational support" and those requiring "proactive support", with Specified Health Guidance provided depending on these categorizations. "Proactive support" is provided among individual in one format from interview, telephone, letters and electronic communication (fax and email, etc.), or as a combination of these.

In the field of research into physical activities, measures offering support for physical activity have also been provided by the use of mobile phone messaging[2]. Furthermore, trials using emails have begun in walking programs in occupational health[3]. We have already noted the short-term effects of guidance and support in improving physical activity when provided by mobile telephone message to healthy young people, and provided by an electronic communication including mobile telephone message to healthy elderly people[4)5)]. Yamatsu, et al. reported that the short-term success rate of intervention in physical activity using the internet and mobile phone terminals is at least 50%[6)]. However, the long-term benefits of intervention in physical activity using the internet and mobile terminal devices are unclear, and the study of its long-term impact, including the development of a methodology for effective intervention, is an issue for the future. While the long-term effects of intervention are still an issue for future consideration, it is considered to be an "effective tool for promoting changes in peoples' behavior"-which is also part of the current Specified Health Guidance.

In Japan, it has been found that 60% of workplace-related illnesses are due to low back pain (LBP)[7)], of which 85% is in the form of Non-Specific LBP (NSLBP), with no specific cause[8)9)]. It has also recently been clarified that psychological and social factors also contribute to NSLBP and that the provision of correct information and an encouraging attitude among those around the subject can contribute to relief from LBP[10)]. In terms of preventing LBP, the effect of guidance using electronic communication was not examined. In our previous study, we conducted a Physical Consultant research (PCo research) in order to verify the effects of email-based guidance provided by physical therapists (the advisors) to workers (the clients) in preventing LBP among workers who had in the past suffered from NSLBP[11)].

In the present study, we used a database of PCo research and analyzed the results of a questionnaire conducted among advisors and clients once intervention had ended, in order to consider a more effective means of email-based guidance using computers and mobile terminal devices.

Methods

Definition of PCo research

This research project was conducted between June 2013 and February 2014, with the aim of verifying the effectiveness of email-based guidance aiming to prevent LBP among worker, and from this, propose a new business model for the utilization of physical therapists in the field of occupational health[11)]. Fig. 1 shows a flow chart of the PCo research. The project allocated 20 currently working advisors with a minimum of three years' of clinical experience to 20 clients, for the purpose of the advisors providing individual guidance on how to prevent LBP by email. Two of the physical therapists who had experience providing advice regarding the prevention of LBP in worker, compiled a basic concept[12)] for the prevention of LBP, with consultations and the content of guidance stored and shared via the cloud computing network at the research secretariat. The email-based guidance intervention was conducted for six months, during which time advisors sent a minimum of eight emails to clients. Moreover, in addition to the regular emails from advisors, the advisors also responded to queries from their clients.

The results of PCo research showed a significant increase in the Work Ability Index (WAI)[13)] which is used to express how skillfully each client is engaging in his/her tasks, along with a tendency towards improvement within the Fear-Avoidance Beliefs Questionnaire (FABQ)[14)] which expresses the subject's state of mind in regard to avoiding the fear of LBP, subsequent to the email-based guidance. In the present study, the Helsinki Declaration was fully adhered to in the use of the PCo research database and no individuals were identified.

Details of the questionnaire

The questionnaire was conducted after completion of the email-based guidance intervention. Questions asked to advisors included: "1) Did you need personal information about the client? (Y/N)"; "2) Number of days taken for the advisor to respond to a question from the client (No. of days)"; "3) Time spent on forming a response by the advisor to a question from a client (No. of minutes)"; "4) Number of responses by email by client to advisor (No. of responses)"; "5) Ideal amount of time spent by advisor in order to come up with a response to a question from a client (from the advisor's perspective) (No. of minutes)"; "6) Details of questions not related to LBP"; "7) No. of clients it would be possible to respond to in one month (No. of responses)"; and "8) Problems with the PCo research (from the advisor's perspective)". Questions 6) and 8) required a free response.

Questions asked to clients included: "1) Do you think that the advice provided by your advisor in emails was helpful in preventing LBP? (Y/N)"; and "2) Would you like to use email-based guidance again? (Y/N)".

The physical therapists dispatched by the research secretariat implemented a lecture for 90 minutes in regard to the prevention of low back pain for company employees. At this time, an explanation of the Physical Consultant research (PCo research) was provided orally, with those giving consent appointed as subjects (clients).

↓

Clients who gave their consent were allocated to a responsible physical therapist (advisor), in regard to whom, the clients' personal information was not disclosed. Personal information about the advisors was also not provided to the clients.

↓

Outline of Email-based guidance

Period	No. of times*	Advisor	Client
Start	1st time	Advisor sends email to client, providing guidance based on questions submitted by client.	Receives email from advisor, and sends questions to advisor.
Two weeks	2nd time		
First month	3rd time		
Second month	4th time		
Third month	5th time		
Fourth month	6th time		
Fifth month	7th time		
Sixth month	8th time		

↓ ↓

Survey on completion*1
Research secretariat implements questionnaire survey in regard to advisors in order to analyze issues related to the email-based guidance.

Survey on completion*2
Research secretariat implements questionnaire survey in regard to clients, in order to ascertain effectiveness of email-based guidance.

Fig. 1 Physical Consultant Research Flow Chart

Advisors: Physical therapists, Clients: Worker, Research secretariat: the Japanese Study Group of Physical Therapy in Occupational Health.

No. of times*: Basic number of times emails sent to clients by advisors. If the client asks questions, the number of times emails and responses are sent may increase based on the details of the advice sought and provided.

Survey on completion*: Data from both surveys on completion (1 and 2) implemented in regard to advisors and clients was utilized in this study.

Questions 3) and 5) for the advisors were compared using the Mann-Whitney U-test. The statistical software used was IBM SPSS Statistics ver. 19, with statistical significance defined at 5%.

Results

The results of the questionnaire survey conducted in regard to advisors are shown in Table 1. Since questions 6) and 8) required a free response, similar responses were compiled and the record shows responses in the order of popularity. No significant difference was between "Time spent on forming a response by the advisor to a question from a client" and "Ideal amount of time spent by advisor in order to come up with a response to a question from a client" (questions 3) and 5)).

The results of the questionnaire survey conducted in regard to clients revealed that 88% responded "Yes (it was helpful)" to the question "Do you think that the advice provided by your advisor in emails was helpful in preventing LBP?", and 76% responded "Yes (would like to use again)" in response to the question "Would you like to use email-based guidance again?"

Table 1 Results of Questionnaires given to Advisors

	Question	Response
1	Need for personal information about the client	All advisors required personal information from their clients
2	Time taken for the advisor to respond to a question from the client	2.0 ± 0.4 days
3	Time spent on creating a response by the advisor to a question from a client	22.0 ± 9.7 minutes
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8	Problems with the PCo research (from the advisor's perspective)	Need subject's information in advance: n = 4 Not clear whether or not client has seen email: n = 2 Need guidelines and examples for composing emails: n = 2 Need to decide how to follow-up if client does not respond: n = 2 Not clear if information being provided is what client requires: n = 1 Difficult to tell whether guidance is effective: n = 1 Differences in advice given by different advisors; this may cause dissatisfaction among clients: n = 1 Confused about what to do when clients do not respond: n = 1 Difficult to build trust with client due to anonymity: n = 1 Need for quantitative data and tools that allow for shared awareness between client and advisor: n = 1

Discussion

In the present study, we used a database of information from past PCo research and analyzed the results of a questionnaire conducted among advisors and clients once intervention had ended, in order to consider a more effective means of email-based guidance using computers and mobile terminal devices.

In the PCo research, we took care to ensure that the advisors could not identify the clients and that the clients could not identify the advisors even after the study ended. The results of the questionnaire implemented on advisors showed that all advisors stated they required personal information from clients in order to provide email-based guidance. In the field of physical activity research it has been reported that the greater the relevancy of messages sent to subjects in support of physical activities, the more likely it is that the message will be received and acted upon[15]. Obtaining personal information about the client is considered to facilitate the provision of guidance that is more relevant to factors in the client's background. As such, disclosure of personal information is an issue that requires more consideration. During the PCo research, a unified concept of guidance to prevent LBP[10] was provided; however, if intervention is to be considered in indeterminate multiple cases, even if personal information is not available. It will be necessary to compile a manual for email-based guidance methods to ensure a smooth response. Guidance for prevention of LBP needs to include guidance related to physical activity and exercise, as well as provisions for psychological and social factors such as FAB[16]. When giving individual advice, it is easy to respond to individual psychological and social factors. However, when giving guidance to a group, it is more difficult to focus on individual psychological and social factors, and as such, is an issue that will require consideration in the future.

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腰痛予防を目的とした理学療法士によるメール指導の現状と課題

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―キーワード―
理学療法士，腰痛，産業保健

腰痛は，最も仕事に支障をきたしやすい疾患であり，いかに腰痛を予防し減らしていくかという職場での対策の確立が不可欠となっている．我々は以前に，労働者（以下，相談者）の腰痛予防を目的として理学療法士（以下，指導者）によるメール指導効果を検討するためにPhysical Consultant研究（以下，PCo研究）を実施した．PCo研究では，相談者の労働能力適応指標および腰痛恐怖回避思考の有意な改善を認めた．本研究の目的は，コンピューターや携帯端末機器を使用したメール指導に関して，より効果的な方法を検討することである．方法は，PCo研究のデータベースを用い，この研究で行われた指導者と相談者へのアンケート調査結果を分析することとした．結果，1人の指導者が同時期に5名の相談者の相談に対応可能なことが明らかとなった．相談者からは，腰痛予防に関連する内容だけではなく，他の筋骨格系の問題，生活習慣や家族の介護に関する相談があった．理学療法士は，これらの相談に対応できる最適な職種として考えられた．より多数の相談者および効果的なメール指導を行うにあたっては専用のシステム開発が必要と考えられた．

利益相反：利益相反基準に該当無し

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Original Article

Psychological detachment from work during non-work time: linear or curvilinear relations with mental health and work engagement?

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Abstract: This study examined whether a higher level of psychological detachment during non-work time is associated with better employee mental health (Hypothesis 1), and examined whether psychological detachment has a curvilinear relation (inverted U-shaped pattern) with work engagement (Hypothesis 2). A large cross-sectional Internet survey was conducted among registered monitors of an Internet survey company in Japan. The questionnaire included scales for psychological detachment, employee mental health, and work engagement as well as for job characteristics and demographic variables as potential confounders. The hypothesized model was tested with moderated structural equation modeling techniques among 2,234 respondents working in the tertiary industries with regular employment. Results showed that psychological detachment had curvilinear relations with mental health as well as with work engagement. Mental health improved when psychological detachment increased from a low to higher levels but did not benefit any further from extremely high levels of psychological detachment. Work engagement showed the highest level at an intermediate level of detachment (inverted U-shaped pattern). Although high psychological detachment may enhance employee mental health, moderate levels of psychological detachment are most beneficial for his or her work engagement.

Key words: Psychological detachment, Mental health, Structural equation modeling, Work engagement, Curvilinearity

Introduction

In recent years, scholars have argued that not only on-job experiences (how employees spend their working time) but also off-job experiences (how they spend their private or leisure time) are crucial for understanding employee well-being[1)]. More specifically, better knowledge of off-job recovery from the demands experienced during working time is imperative[2)]. Recovery can be defined as a process during which individual functional systems that have been

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called upon during a stressful experience return to their initial, pre-stressor level[3]. Recovery can be regarded a process opposite to the strain process, during which the detrimental effects of stressful situations are alleviated or eliminated. Recovery is also regarded as an explanatory mechanism in the relation between acute stress reactions and chronic health impairment[4]. Certain experiences outside of work can help in alleviating reactions to work demands[5–7]. These so-called recovery experiences consist of psychological detachment, relaxation, mastery, and control[8]. Psychological detachment; i.e., the ability of individuals to mentally "switch off" from work by not doing work-related tasks and not thinking about work during non-work time, is considered the most crucial recovery experience for protecting one's well-being regarding job-related recovery[2, 9].

In the context of respites from work, detachment has been described as an "individual's sense of being away from the work situation"[10]. Psychological detachment has been further characterized as not being involved in work-related activities, such as phone calls, e-mails, or other work-related tasks, during off-work time[8]. Psychological detachment from work extends beyond the pure physical absence from the workplace during off-job time and abstaining from job-related tasks. It implies leaving the workplace behind oneself in psychological terms[11].

The relation between psychological detachment and well-being can be explained by COR theory[12] and the Effort-Recovery Model[3]. Conservation Of Resources (COR) theory asserts that an individual aspires to preserve, protect, and build resources. Resources are characterized as objects, conditions, personal characteristics, or energies that have specific importance for the individual. According to COR theory, stress occurs when individuals are threatened with resource loss, actually lose resources, or fail to gain resources following resource investment. The inability to replenish energy resources may lead to long-term fatigue, which hampers normal functioning in many aspects in daily life, including work. Thus, to recover from stress, individuals have to gain new resources and restore threatened or lost resources. Psychological detachment can contribute to gaining new resources and restore threatened or lost resources.

The Effort-Recovery Model[3] holds that effort expenditure at work leads to load reactions such as fatigue or physiological activation. Load reactions can accumulate and lead to impaired health and well-being, unless individuals can recover from work. By no longer being exposed to job-related demands, load reactions can return to pre-stressor levels, and recovery can occur before the next working period starts. This implies that recovery strategies such as psychological detachment during off-work time can be an opportunity to return to and stabilize at a baseline level. Thus, both the Effort-Recovery Model and COR theory suggest two complementary processes by which recovery occurs. First, it is important to refrain from work demands and to avoid activities that call upon the same functional systems or internal resources as those required at work. Second, gaining new internal resources such as energy, self-efficacy or positive mood will additionally help to restore threatened resources[8].

Previous studies that examined the relation between psychological detachment and well-being have revealed that psychological detachment is positively associated with mental health and negatively associated with job stress and burnout[6, 8, 11, 13, 14]. Therefore, we expect that a higher level of psychological detachment during non-work time will be associated with better mental health (Hypothesis 1).

Regarding positive aspects of employee well-being, the present study focuses on work engagement, which refers to a positive, fulfilling, work-related state of mind that is characterized by vigor, dedication, and absorption[15]. Previous studies have shown that psychological detachment is positively associated with work engagement[16−18], because detachment may contribute to the prevention of continued resource drain and restoration of resources[18]. If employees do not unwind from one's work, depleted resources can lead to low work engagement. Thus, we can assume that low levels of psychological detachment are associated with low work engagement.

However, the relation between psychological detachment and work engagement appears to be more complex. For instance, Shimazu *et al.*[19] showed a negative relation between these variables, suggesting that switching off mentally during off-job time did not improve work engagement, but rather decreased it. When individuals are highly detached from their jobs during off-job time, they may feel difficulty in "switching on" again in the next morning[14], and they may need more time to mobilize their energy for their job, which results in impaired work engagement.

These findings suggest that (very) low and (very) high levels of psychological detachment will be detrimental to work engagement. As a result, moderate levels of psychological detachment will be associated with the highest levels of work engagement. All these findings imply non-linear rather than linear relations between detachment and work engagement, which is in line with Warr's (1994) assumptions on work[20], mental health and well-being. Accordingly, we expect that psychological detachment will have a curvilinear relation (inverted U-shaped pattern) with work engagement (Hypothesis 2).

Method

Study population

An Internet research company with 1.5 million registered research volunteers aged 20–69 years, was used to conduct a large Internet-based cross-sectional survey on occupation, health and well-being in 2011. We randomly selected 106,250 volunteers from 201,170 monitors, living in three greater metropolitan areas of Japan (23 wards of Tokyo, the City of Osaka, and the City of Nagoya). On March 25, 2011, the selected volunteers were invited to take part in the study via an e-mail containing a link to the survey. Participants received online shopping points as an incentive for participation. In order to prevent double registration, e-mail addresses were checked and a link to the questionnaire was disabled once the survey was completed. On March 31, 2011, the survey was closed when more than five thousand participants responded (a total of 5,860 surveys were collected). Therefore, a specific response rate could not be calculated for this survey.

Our respondents were very close to the people living in 23 wards of Tokyo, the City of Osaka, and the City of Nagoya in terms of mean age (45.2 years in our respondents, 43.9 in Tokyo, 44.8 years in Osaka, and 43.8 years in Nagoya), gender (50.8% in our respondents, 50.7% in Tokyo, 51.5% in Osaka, and 50.7% in Nagoya), and employment status (46.5% regular employment in our respondents, 46.1% in Tokyo, 46.2% in Osaka, and 50.1% in Nagoya). However, our respondents had higher educational level (40.9% undergraduate or higher) than those living in Tokyo (33.2%), in Osaka (20.8%), and in Nagoya (26.0%)[21, 22].

In our respondents, the proportion of respondents working within primary industries (e.g., agriculture, forestry, and fisheries) and secondary industries (e.g., mining, manufacturing, and constructions) was extremely low (0.1% and 7.6% respectively). Therefore, we analyzed responses only from those individuals working in tertiary industries (e.g., transport and postal activity, wholesale and retail trade, accommodations, eating and drinking services, finance and insurance, advertising, education and learning support, and medical, health care and welfare). Individuals with a reported age of either <20 years or ≥65 years, those with non-regular employment, or shift workers were excluded[23–25]. A total of 2,234 participants were retained and included in the analysis. The mean age of the participants was 41.7 years (SD=11.3). Of the participants, 63.9% were male, 54.4% were married, 55.9% had a university degree or higher, and 12.2% worked more than 60 hours per week.

Measures

Psychological detachment

Psychological detachment was assessed using the corresponding subscale of the Japanese version of the Recovery Experience Questionnaire[8, 19], consisting of four items (i.e., “I forget about work,” “I don’t think about work at all,” “I distance myself from my work,” and “I get a break from the demands of work”). All items were scored on a five-point Likert scale, ranging from 1 (do not agree at all) to 5 (fully agree). Responses for the 4 items were summed to get a scale score. Cronbach’s alpha coefficient was .86.

Mental health

Mental health was assessed using the corresponding subscale of the SF-36 version 1.2[26–28], consisting of five items (i.e., “Have you been a very nervous person?”, “Have you felt so down in the dumps that nothing could cheer you up?”, “Have you felt calm and peaceful? (reversed)”, “Have you felt downhearted and blue?”, and “Have you been a happy person? (reversed)”). All items were scored on a six-point Likert scale, ranging from 1 (all of the time) to 6 (none of the time). We used the SF-36 mental health summary score as a measure of mental health (Range: 0–100)[29]. Cronbach’s alpha coefficient was .84.

Work engagement

Work engagement was assessed using the short form of the Utrecht Work Engagement Scale (UWES)[15], which has been validated in Japan[30]. The UWES includes three subscales that reflect the underlying dimensions of engagement: Vigor (3 items; e.g., “At my job, I feel strong and vigorous”), Dedication (3 items; e.g., “I am enthusiastic about my job”), and Absorption (3 items; e.g., “I am immersed in my work”). All items are scored on a seven-point Likert scale ranging from 0 (never) to 6 (always). Responses for the 3 items each were summed to get a scale score. Cronbach’s alpha coefficients were .87 for vigor, .84 for dedication, and .86 for absorption.

Potential confounders

We controlled for two types of potential confounders; i.e., (1) job characteristics and (2) demographic characteristics. Their relation with detachment and our outcome measures is well-established in the literature[4, 9, 11].

Job characteristics were assessed using three scales of the Brief Job Stress Questionnaire (BJSQ[31]): job demands, job control and workplace support. The first two scales consisted of 3 items each, for instance "My job requires working hard" and "I have influence over the pace of my work". Workplace support consisted of 6 items: 3 items for supervisor support and 3 items for coworker support. To receive a more parsimonious model and to avoid multi-collinearity, we combined the two subscales in overall workplace support due to a high bivariate correlation ($r=0.59$; $p<.001$). All items were scored on a four-point Likert scale, ranging from 1 (disagree) to 4 (agree). Cronbach's alpha coefficients were .81 for job demands, .85 for job control, and .86 for workplace support.

Demographic characteristics such as age, gender, marriage, education, and working hours per week were also included as potential confounders in the questionnaire.

Data analyses

To test the hypotheses, we conducted moderated structural equation modeling (MSEM) analyses, using the AMOS software package[32]. We preferred MSEM to hierarchical regression analyses, because MSEM allows multivariate testing of outcomes, allows assessing and correcting for measurement error, and provides measures of fit of the models under study. We followed the procedure proposed by Mathieu *et al.*[33] as described by Cortina *et al.*[34]. Linear psychological detachment and mental health had only one indicator that was the standardized (centered) scale score of the respective factor[33]. The indicator of the latent curvilinear psychological detachment was the squared term of the standardized (centered) scale score of psychological detachment. Work engagement had three indicators (i.e., vigor, dedication, and absorption). Correlation between linear psychological detachment and curvilinear one was constrained to be zero, whereas mental health and work engagement were allowed to correlate. The paths from the latent exogenous factors to their indicators were fixed using the square roots of the scale reliabilities, and the error variances of each indicator were set equal to the product of their variances and 1 minus their reliabilities. See Fig. 1 for our hypothesized model. For more details regarding the calculation of the reliability score of the curvilinear term,

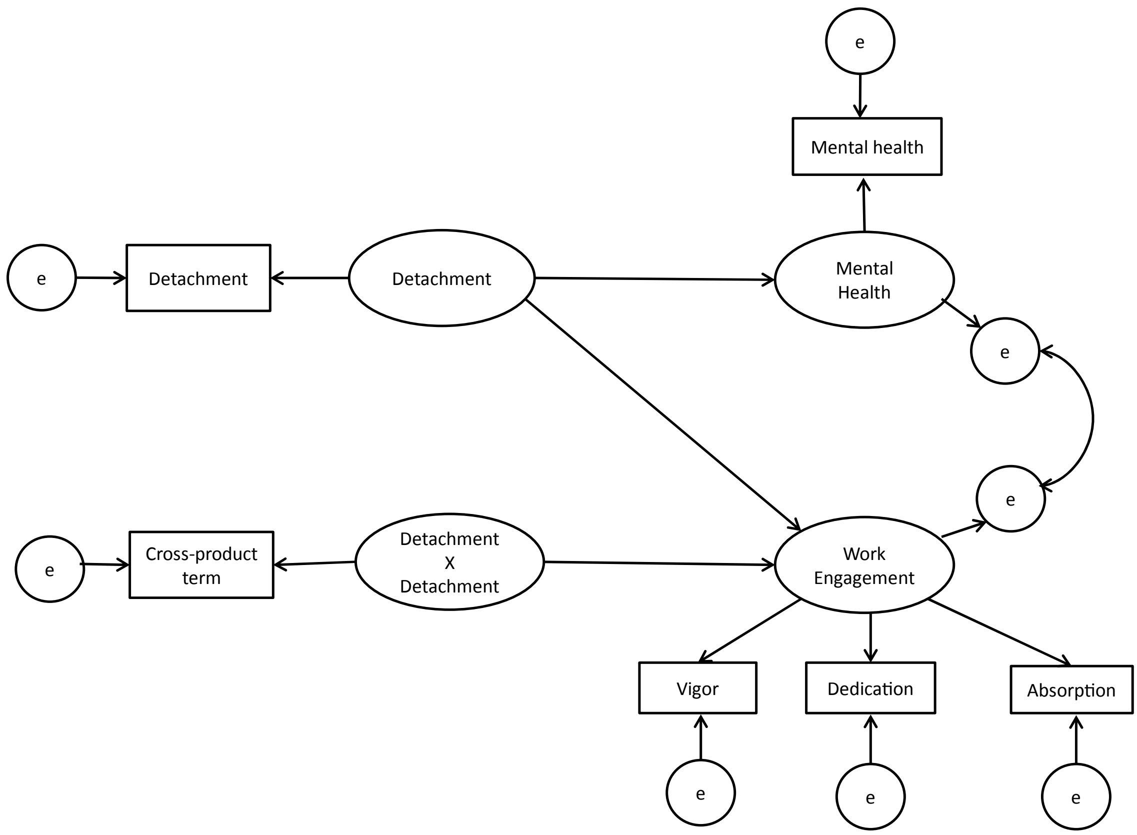

Fig. 1. Hypothesized model (Model 1).
Note: e = error.

we refer to Cortina *et al.*[34].

The fit of the models was assessed with the chi-square statistic, the goodness-of-fit index (GFI), the comparative fit index (CFI), the non-normed fit index (NNFI), and the root-mean-square error of approximation (RMSEA). It is suggested that GFI, CFI, and NNFI values that exceed .90 and RMSEA values as high as .08 are indicative of acceptable fit[35].

Ethics statement

This study was approved by the medical/ethics review board of the Japan Labour Health and Welfare Organization and The University of Tokyo medical department.

Results

Simple statistics

Zero-order correlation coefficients are shown in Table 1. Psychological detachment was positively correlated with mental health (r=.22, p<.001), and negatively correlated with vigor (r=−.04, p<.05), dedication (r=−.06, p<.01), and absorption (r=−.14, p<.001).

Results of MSES analyses

Results of the MSEM-analyses showed that the hypothesized model (Model 1) fits to the data ($\chi^2(8)$=236.72, p<.001, GFI=.97, NNFI=.93, CFI=.96) although RMSEA value exceeded .08 (RMSEA=.11). In line with Hypothesis 1, linear psychological detachment was positively related to mental health (β=.24, p<.001). As to Hypothesis 2, both linear and curvilinear psychological detachment were negatively related to work engagement (β=−.10, p<.001 and β=−.06, p<.01, respectively).

To ensure that no curvilinear relation existed between psychological detachment and mental health in addition to linear one, we examined the alternative model that adds the path from curvilinear psychological detachment to mental health. The model fit of the alternative model (Model 2: $\chi^2(7)$=216.11, p<.001, GFI=.97, NNFI=.92, CFI=.97, RMSEA=.12) was similar to one of the hypothesized model. However, the chi-square difference test, comparing the hypothesized model (Model 1) with the alternative model (Model 2), shows a significant improvement in model fit ($\Delta\chi^2(1)$=20.61, p<.001). This means that the alternative model (Model 2), including the path from curvilinear psychological detachment to mental health, offers a better account of the data than the hypothesized model (Model 1). Therefore, we decided to adopt the alternative model (Model 2) in further examination.

Table 1. Descriptive statistics for the key study variables (N=2,234)

	Variable	Range	Mean	SD	1	2	3	4	5	6	7	8	9	10	11	12
1	Age	20–64	41.74	11.31												
2	Gender[a]	0–1	.64	.48	−.10***											
3	Marriage[b]	0–1	.54	.50	−.41***	.31***										
4	Education[c]	0–1	.56	.50	−.08***	−.19***	−.03									
5	Working hours (per week)[d]	0–1	.12	.33	−.06**	−.15***	−.04*	.03								
6	Job demands	3–12	8.20	2.22	−.14***	−.07**	.02	.09***	.26***							
7	Job control	3–12	8.10	2.02	.18***	−.02	−.10***	.00	−.06**	−.16***						
8	Workplace support	6–24	15.20	3.89	−.03	.03	−.05*	−.01	−.01	−.02	.30***					
9	Psychological detachment	4–20	13.77	3.53	.01	.06**	.07**	−.05*	−.11***	−.25***	.07***	.05*				
10	Mental health	0–100	59.93	19.37	.14***	−.04*	−.12***	.03	−.09***	−.22***	.25***	.35***	.22***			
11	Vigor	0–18	6.93	3.67	.20***	.03	−.11***	.01	.01	.01	.31***	.30***	−.04*	.31***		
12	Dedication	0–18	8.25	3.77	.17***	.05*	−.09***	.01	.05*	.13***	.29***	.30***	−.06**	.25***	.82***	
13	Absorption	0–18	6.97	3.87	.14***	.00	−.08***	.03	.06**	.14***	.27***	.24***	−.14***	.18***	.79***	.83***

Note: *p<.05 **p<.01 ***p<.001. SD: Standard Deviation. [a] Gender was coded as 1 (men) and 0 (women). [b] Marriage was coded as 1 (yes) and 0 (no). [c] Education was coded as 1 (university or higher) and 0 (college or lower). [d] Working hours per week was coded as 1 (60=<) and 0 (<60).

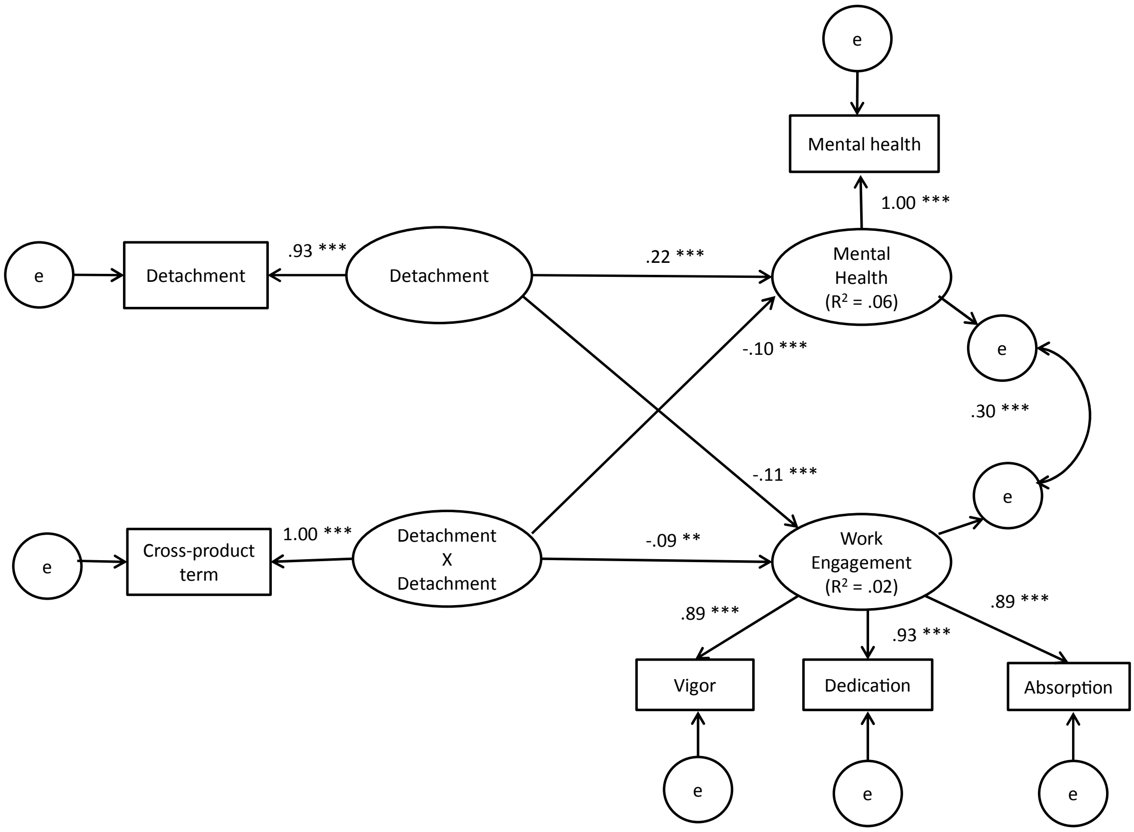

Fig. 2. Standardized solution (Maximum Likelihood estimates) of the final (alternative) model (Model 2: N=2,234).
Note: e=error. ***p<.001, **p< .01, *p<.05.

As can be seen in Fig. 2, linear psychological detachment was significantly and positively related to mental health (β=.22, p<.001) whereas curvilinear psychological detachment was also significantly but negatively related to it (β=−.10, p<.001). In addition, both linear and curvilinear psychological detachment were significantly and negatively related to work engagement (β=−.11, p<.001 and β=−.09, p<.01, respectively). Please note that the results regarding the curvilinear relationship between psychological detachment and work engagement were similar in all three sub dimensions of the construct (i.e., vigor, dedication, and absorption).

Regarding the curvilinear relation between psychological detachment and mental health, Fig. 3 shows that initially there is a positive relation: more detachment is associated with better mental health. However, at high levels of psychological detachment, the positive relation between psychological detachment and mental health became less prominent, and even seems to disappear. Mental health did not increase further and remained at a high level.

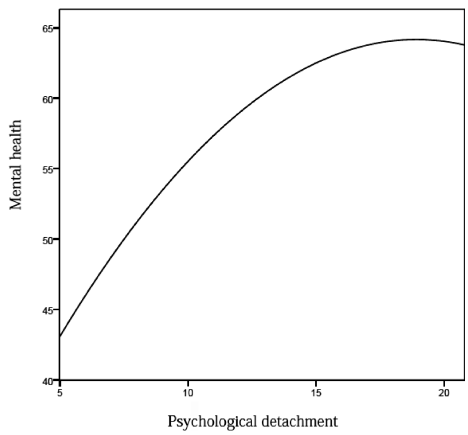

Fig. 3. Curve-fitting between psychological detachment and mental health.

With regard to the curvilinear relation between psychological detachment and work engagement, Fig. 4 shows that moderate levels of psychological detachment were associated with the highest levels of work engagement, whereas

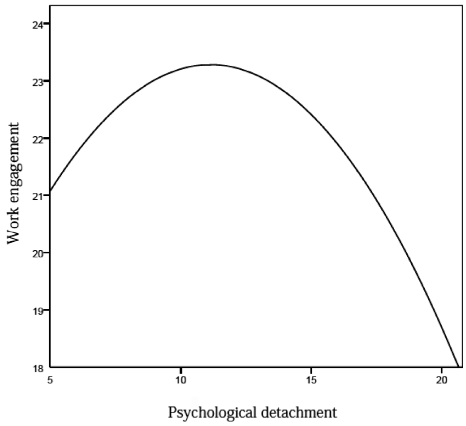

Fig. 4. Curve-fitting between psychological detachment and work engagement.

very low and very high detachment were associated with lower levels of work engagement (i.e., inverted U-shaped pattern).

In a final step, we conducted additional analysis to control for potential confounders (i.e., age, gender, marriage, education, working hours, job demands, job control, and workplace support). Specifically, each control variable was included in the alternative model (Model 2) as a manifest variable simultaneously and was allowed to relate to all variables in the model. After controlling for confounding variables, the path coefficients were virtually the same as those of the alternative model (Model 2), but the model fit decreased (χ^2 (35)=1538.06, p<.001, GFI=.91, NNFI=.53, CFI=.82, RMSEA=.14). These results indicate that the added relations of the control variables to the model variables were weak. Importantly, many control variables did not significantly affect the structural paths in the model (i.e., 18 out of 48 paths were not statistically significant). Therefore, the control variables were removed from the final model in Fig. 2.

Discussion

The aim of this large cross-sectional Internet survey study was to examine whether higher levels of psychological detachment during non-work time would be associated with improved employee mental health (Hypothesis 1). We also examined whether psychological detachment would have a curvilinear relation (i.e., inverted U-shaped pattern) with work engagement (Hypothesis 2). Examination of the curvilinear relation was novel, because prior research on the function of psychological detachment on work engagement is inconsistent in this respect[16–19].

As far as the relation between psychological detachment and mental health is concerned, MSEM revealed that not only linear psychological detachment (β=.22, p<.001) but also curvilinear detachment (β=−.10, p<.001) was significantly related to mental health. This result was contrary to our expectation. Examining Fig. 3, the positive relation between psychological detachment and mental health flattened after higher levels of psychological detachment. This pattern of findings suggests that mental health initially improves when people psychologically detach. However, employee mental health does not benefit any further from extremely high levels of psychological detachment. It is important to note that mental health does not suffer at such very high levels of psychological detachment. Although most previous studies showed that higher levels of psychological detachment during non-work time were associated with better employee mental health[6, 8, 11, 13], our result suggests that the favorable effect of psychological detachment may have an upper limit on mental health, at least among our participants. Future research needs to examine under which conditions and for whom psychological detachment has such a curvilinear relation with mental health.

As to the relation between psychological detachment and work engagement, we also found a curvilinear relation. Moderate levels of psychological detachment were associated with highest levels of work engagement, whereas very low and very high psychological detachment was associated with lower levels of work engagement (i.e., inverted U-shaped pattern). Very low levels of psychological detachment may drain one's resources and inhibit resource restoration, whereas very high levels of psychological detachment may require a longer time to get back into "working mode" in the next morning[9]. These may negatively impact work engagement, particularly at high levels of detachment. Finally, it is worth noting that the curvilinear relation between psychological detachment and work engagement resembles (albeit at a weaker level) a previously found relation between psychological detachment and job performance in earlier research[14]. Given that both of these are more strictly work-related variables, the current finding may have implications for future research on the topic.

Limitations and suggestions for future research

Next to several strengths such as a large sample size and sufficient study power, there are also several limitations of this study. First, we used self-report survey data. Self-report measures may be biased due to, for example, negative affect. Common method variance might have affected the results, suggesting that the true associations between variables might be weaker than those observed in this study. Although several studies have shown that these influences are not as high as could be expected[36–38], our findings should be replicated using more objective measures (e.g., peer-ratings of mental health and work engagement) in the future.

Second, we used a cross-sectional study design, which precludes making causal inferences. For instance, our data showed that psychological detachment was related to better mental health. This might indicate that more psychological detachment leads to better mental health. It might also be that individuals enjoying better mental health are more likely to detach themselves from their work. Based on the cross-sectional analyses of the current study, it can only be concluded that psychological detachment is related to mental health and well-being. More longitudinal research is needed to uncover the causal sequence in the relation between psychological detachment and its consequences. However, it should be noted that there is a growing body of literature that demonstrates longitudinal effects of psychological detachment on health and well-being, particularly at day-level[39–42]. They support our causal inferences from both theoretical and empirical viewpoints.

Third, our data were collected from people living in three greater metropolitan areas of Japan (23 wards of Tokyo, the City of Osaka, and the City of Nagoya), which requires caution regarding the generalizability of our findings. Our sample may not represent other working populations quite well. Therefore, further studies are necessary to examine whether our results are applicable to workers in local areas.

Fourth, our data were collected via the Internet, which again requires caution regarding the generalizability of our findings. It has been claimed that the socioeconomic and educational status of the average Internet user is usually greater than that of the general population[43]. Indeed, our participants reported higher educational status than those completing nationwide paper-and-pencil surveys in Japan[44] and those living in Tokyo, in Osaka, and in Nagoya[21, 22]. Thus, similar to typical Internet studies, self-selection might be a limitation of the present study.

Finally, psychological detachment did not have much explanation for outcomes in our participants. Specifically, linear and curvilinear psychological detachment explained successively 6% and 2% of the variances of mental health and work engagement in Model 2. One possible explanation is that we did not examine the combined effects of psychological detachment and other types of recovery experiences. Until now, only bivariate associations of recovery experiences with outcome variables have mainly been investigated. However, in reality, it is less likely that people use either type of recovery experience exclusively. Rather, they may use various types of recovery experiences simultaneously given the positive correlations among them (e.g., r=.16−63 by Sonnentag[8], and r=.26−.70 by Shimazu *et al.*[19]). Hence, it is important to examine the combined as well as independent associations of each type of recovery experience with well-being in employees. According to COR theory[12], employees using various type of recovery experiences simultaneously are assumed to experience better well-being because multiple recovery experiences may provide more opportunity for recovery from resource loss and for resource gain. Another possible explanation is that we did not consider conditions under which employees use psychological detachment. This suggests the possibility that psychological detachment may not be favorable for everybody and in all situations[45]. For instance, employees who experience their jobs as highly meaningful and enjoyable might find detachment difficult to achieve, but lack of detachment might be less of a problem for such people. Thus, job features might moderate the relation between psychological detachment and well-being. Future research needs to examine the conditions under which psychological detachment can have more favorable effects.

Implications for practice

Our findings have some implications for practice. A first implication is that psychological detachment during non-work time is associated with employee mental health and work engagement *in different ways*.

With regard to employee mental health, higher levels of detachment would facilitate better mental health (although the favorable effect of detachment had limitations). It is important that both organizations and supervisors should support employee detachment by advising that employees be as unavailable as possible (e.g., via e-mail, texting or phone) during their non-work time. It might be beneficial for workers to detach from work if they do not use their smartphones or tablets for work-related issues during free time[46–48]. However, it might also be possible that checking one's work e-mails helps to detach from work in particular circumstances. For example, if s/he is unsure whether s/he has forgotten to inform a colleague about an important work-related issue, to check the sent box of his/her e-mail account might help him/her thereafter to detach from work. Further research needs to examine whether the use of communication devices such as smartphones or tablets during non-work time can be beneficial or not for one's detachment from work. Organizations and supervisors can also support employee detachment by not initiating work-related communication with their employees during non-work time, thereby allowing detachment to occur[14]. Supervisors can act as role models in this respect by not being available during non-work time. This is particularly important in a country like Japan, because those who are in charge of changing long working culture in Japan are often work addicts themselves[49]. Furthermore, improving working conditions to achieve adequate levels of job demands (e.g., reduce time pressure) can be a promising avenue to facilitate psychological detachment because high job demands can inhibit psychological detachment during off-work time[2].

It is also important for employees who are at risk for workaholism (i.e., working excessively with an obsessive manner[50]) to modify this tendency, since it inhibits psychological detachment[2]. Training programs that focus on time management and problem solving skills might be helpful, because workaholic employees take on more work than they can handle and accept new tasks before completing previous ones[51]. Rational emotive therapy[52] might be also helpful, since workaholic people suffer from the belief that they should be perfect[53].

With regard to work engagement, the relation with psychological detachment is more complex and suggest a different practical implication: Moderate levels of psychological detachment would be associated with the highest levels of work engagement. Although operationalizing the optimal level of psychological detachment seems to be not very easy, it should be noted that thinking about work may not be necessarily negative per se[9, 54]. Positively reflecting about one's work (e.g., thinking about a recent success or about an inspiring goal) might even improve work engagement, but this thinking should not be too much − there seems to be an upper limit for work reflection. Future research needs to clarify the preferable type and amount of work-related thoughts during off-job time to improve work engagement.

Conclusion

Although higher levels of psychological detachment may enhance employee mental health, it seems that moderate levels of psychological detachment are most beneficial for his or her work engagement. In future, more research is needed to address how, and under which conditions, to attain optimal levels of psychological detachment to achieve both better employee mental health and greater work engagement.

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Original Article

Potential risk factors for onset of severe neck and shoulder discomfort (Katakori) in urban Japanese workers

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Abstract: Katakori is a Japanese word, and there is no clear English translation. Katakori consists of two terms, Kata means neck and shoulder, kori means stiffness. Consequently, Katakori is defined as neck and shoulder discomfort or dull pain. Katakori is a major somatic complaint and has a large impact on workers. To examine the association between onset of severe Katakori and potential risk factors in Japanese workers, a prospective cohort study, entitled "Cultural and Psychosocial Influence on Disability (CUPID)", was conducted. Self-administered questionnaires were distributed twice: at baseline and 1 year after baseline. Logistic regression was used to explore the risk factors of onset of severe Katakori. Of those 1,398, the incidence of severe Katakori onset after 1 year was 3.0% (42 workers). Being female (adjusted odds ratio: 2.39, 95% confidence interval: 1.18–4.86), short sleep duration (adjusted odds ratio: 2.86, 95% confidence interval: 1.20–6.82) and depressed mood with some issues at work (adjusted odds ratio: 3.11, 95% confidence interval: 1.38–7.03) were significantly associated with onset of severe Katakori. Psychosocial factors as well as gender difference were associated with onset of severe Katakori. We suggest that mental health support at the workplace is important to prevent severe Katakori.

Key words: Katakori, Prospective study, Risk factors, Japanese workers, Psychosocial factors

Introduction

Katakori is a Japanese word, and there is no clear English translation. Katakori consists of two terms, Kata means shoulder and kori means stiffness. Consequently, Katakori is defined as discomfort or dull pain caused by muscle stiffness around the back of the head and through the shoulders and/or shoulder blades[1]. Katakori is usually classified as one of the cervico-omo-brachial syndrome. The symptoms of Katakori are considered to be close to "neck pain" or "chronic nonspecific neck pain" as expressed in the references[2–4].

Katakori is classified into primary Katakori (essential Katakori) which does not identify any causable disease (organic disorder) and secondary Katakori (symptomatic Katakori) which is caused by disease. Examples of disease

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which can be the cause of secondary Katakori include cervical spine disease, glenohumeral joint disease, cardiovascular disease, pulmonary disease, eye fatigue, temporomandibular arthrosis, and menopausal syndrome[5, 6].

The prevalence of Katakori is 6.1% among males and 13.1% among females in Japan[7], therefore Katakori is a major somatic complaint which is comparable to low back pain and has a large impact on people including workers with subjective symptoms, however, its pathogenesis is still unclear. Furthermore, the association between Katakori and potential risk factors has not been properly assessed in prospective epidemiological research.

There have been reports of several risk factors associated with Katakori: such being female[6−9], using a Visual Display Terminal (VDT)[6] and mental health[9, 10]. These factors have been identified based on the results of cross-sectional studies.

A prospective cohort study, entitled "Cultural and Psychosocial Influence on Disability (CUPID)", was conducted to explore further the impact of cultural and psychosocial influences on musculoskeletal symptoms and associated disability[11, 12]. A cross-sectional analysis of baseline data shows that being female and depressed mood have been associated with severe Katakori in urban Japanese workers[8]. In this study, using one year of follow-up data, we conducted a continued analysis to examine the association between onset of severe Katakori and potential risk factors in urban Japanese workers. To our knowledge, this was the first longitudinal study assessing the potential risk factors for onset of severe Katakori. In this study, we especially focused on severe Katakori since Katakori is a common symptom among Japanese workers.

Subjects and Methods

Data from a 1-year prospective cohort of the CUPID study were used for this analysis. The CUPID study is an international joint research project, which has involved 18 countries. In Japan, ethical approval for the study was obtained from the ethics committees of the University of Tokyo Hospital and review board of the Japan Labour Health and Welfare Organization. All participants provided written informed consent.

The workers around Tokyo including office workers, sales and marketing personnel, transportation workers, and nurses were recruited.

The board of each participating organization was asked to distribute a self-administrated questionnaire along with a cover letter from the study administration office to their workers. Responders were asked to return their completed questionnaires by mail and to provide their names and mailing addresses for direct correspondence from the study administration office for 1-year follow-up purposes.

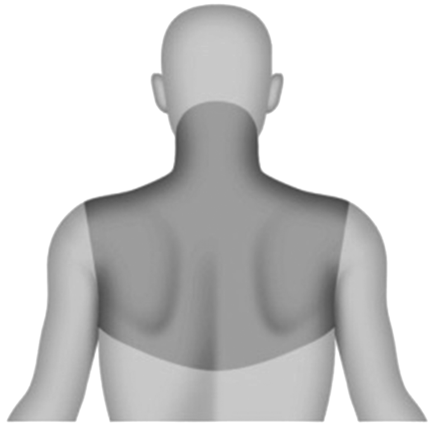

Fig. 1. Diagram showing pain area for Katakori.

The original questionnaire used in the CUPID study was translated into Japanese with some newly designed questions for Japanese workers regarding Katakori. The translation equivalence with the original questionnaire was checked through independent back-translation into English. For the participants, the pain area of Katakori was defined as the back of the head and through the shoulders and/or shoulder blades (Fig. 1). At baseline, respondents were asked about the frequency and severity of Katakori they had experienced during the previous month. The frequency of Katakori was assessed on a 6-point scale (1, always; 2, almost always; 3, often; 4, sometimes; 5, seldom; 6, never); the severity of Katakori was measured on an 11-point numerical rating scale (NRS) ranging from 0 (no Katakori) to 10 (severe Katakori). At follow-up, the frequency of Katakori was assessed using three duration periods (1−6 days, 1−2 weeks, or ≥2 weeks) and the severity of Katakori was measured by NRS.

In addition, the baseline questionnaire assessed individual characteristics (i.e., age, gender, age at the last educational status, body mass index (BMI), hours of sleep, marital status, regular exercise, smoking habits, visual fatigue, dental therapy, dental bite, and outpatient with articular and spine symptoms), ergonomic work demands (period of current service, working hours per week, VDT use, finger repetition, lifting, driving, standing, and work shift), and psychosocial factors (job satisfaction, job control, inadequate break time at work, worksite support, interpersonal stress at work, and experience of depressed mood with an issue at work). Variables were categorized by the same methods previously used in the CUPID study for Katakori association[8]. Age was categorized as <30 years, 30–39 years, 40–49 years or ≥50 years. BMI was calculated by height and body weight recorded in a questionnaire; BMI ≥25 was defined as obesity. Age at the last educational status was categorized as ≤19 years or >19 years; low education was defined as ≤19 years. Regular exercise was defined as physical exercise performed more than twice a week for 20 minutes or longer during the previous 12 months. Short sleep duration was defined as an average of <5 hours. Low experience in current job was defined as <1 year of current service. Sixty hours of working hours per week was defined as high work demand. VDT was defined as work using the computer display for ≥4 hours per shift. Lifting was defined as a work to lift or move ≥25 kg (object or person) by hand. Driving was defined as ≥4 hours of car or truck driving per shift. Standing was defined as ≥4 hours standing per shift. Work shift was defined as irregular work shift such as night shift. To assess the level of job satisfaction, responders were asked, "Considering everything, how satisfied are you with your work?" Answers were the following four choices: "Very satisfied", "Satisfied", "Not well satisfied" and "Not satisfied at all". Low job satisfaction was defined as an answer of "Not well satisfied" or "Not satisfied at all". To assess the level of job control, responders were asked, "How much control do you have in your work?" These items had four response options: often, sometimes, seldom, and never/almost never. Low job control was defined as an answer of "seldom" or "never/almost never". To assess the level of worksite support, responders were asked, "When you have difficulties in your work, how often do you get help and support from your colleagues or supervisor/manager?" This item had five response options: often, sometimes, seldom, never, and not applicable. Low worksite support was defined as an answer of "seldom" or "never" for worksite support. Depressed mood with some issues at work was defined as experience of that in past 12 months.

The follow-up questionnaire was distributed 1 year after the baseline assessment, and the second questionnaire was sent only to the participants who returned the first one with their written consent of participating. Therefore, those who did not return a questionnaire did not participate in the study any longer.

The outcome of interest was onset of severe Katakori during the 1-year follow-up period. In this study, severe Katakori was defined as frequency more than 2 weeks in the previous month and as severity with NRS more than 7

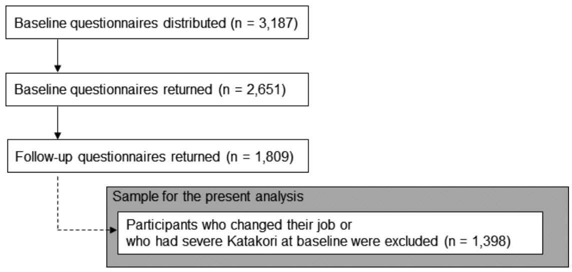

Fig. 2. Flowchart of the sample selection.

points at the follow-up. Incidence was calculated for the participants who reported no severe Katakori at baseline, as we defined severe Katakori as frequency more than often and as severity with NRS more than 7 points during the previous month. Participants were excluded from the analysis if they had changed their job.

For statistical analysis, in addition to compiling descriptive statistics, logistic regression was used to explore the associations between risk factors and onset of severe Katakori. Results of logistic regression analyses were summarized by odds ratios (ORs) and the respective 95% confidence intervals (CIs). For the assessment of potential risk factors, crude ORs were initially estimated. Factors with p-values <0.1 were considered to be potential risk factors. We conducted a multivariate logistic regression analysis using potential risk factors in the model and then using a stepwise selection method in which terms were retained if they reached the 0.05 level of significance. All statistical tests were two-tailed, and conducted with a significance level of 0.05. The software package SAS Release 9.3 (SAS Institute Inc., Cary, NC) was used for statistical analyses.

Results

The baseline questionnaire was distributed to 3,187 participants and was completed by 2,651 participants. The following year, 1,809 participants successfully completed and returned the follow-up questionnaire, thereby yielding a follow-up rate of 68.2%.

Participants (n=411) were excluded from the analysis if they had severe Katakori at baseline (n=330) or those who changed their job (n=81). Thus, a total of 1,398 participants were included in the present analysis (Fig. 2).

Mean (SD: standard deviation) age was 37.3 (10.0) years, of which 1,398 of 73.8% of participants were male. Jobs were nurses (21%), office workers (15%), sales and marketing personnel (21%) and transportation operators (43%). [Table 1] The incidence of onset of severe Katakori

Table 1. Characteristics of responders

Characteristics	Severe Katakori	Non-Severe Katakori	Total
N (%)	42 (3.0%)	1,356 (97.0%)	1,398
Gender			
Male, n (%)	21 (2.0%)	1,011 (98.0%)	1,032 (73.8%)
Female, n (%)	21 (5.7%)	345 (94.2%)	366 (26.2%)
Age, mean (SD)	37.1 (9.0)	37.3 (10.0)	37.3 (10.0)
Job type			
Transportation operative	15 (2.5%)	585 (97.5%)	600 (43.0%)
Sales/marketing personnel	5 (1.7%)	289 (98.3%)	294 (21.0%)
Nurse	16 (5.4%)	278 (94.6%)	294 (21.0%)
Office workers	6 (2.8%)	204 (96.7%)	211 (15.1%)

Table 2. Crude odds ratios of the risk factors for onset of severe Katakori

Risk factors	%	Crude odds ratio (95%CI)	*p* value
Gender			
Male	73.8	1.00	
Female	26.2	2.92 (1.58–5.42)	0.001
Age (yr)			
<30	25.5	1.00	
30–39	37.3	1.79 (0.74–4.33)	0.197
40–49	22.6	1.64 (0.62–4.35)	0.324
≥50	14.6	1.51 (0.50–4.57)	0.462
Outpatient with articular and spine			
No	97.2	1.00	
Yes	2.8	0.82 (0.11–6.14)	0.850
Outpatient with dental therapy			
No	92.7	1.00	
Yes	7.3	1.35 (0.47–3.87)	0.537
Wrong dental bite			
No	83.8	1.00	
Yes	16.2	1.76 (0.85–3.65)	0.130
Visual fatigue			
No	56.3	1.00	
Yes	43.7	2.20 (1.15–4.21)	0.017
BMI			
<25 kg/m^2	84.0	1.00	
≥25 kg/m^2	16.0	1.50 (0.71–3.19)	0.291
Current smoking			
No	56.4	1.00	
Yew	43.6	1.44 (0.78–2.66)	0.245
Age at last educational status **(yr)**			
≥20	62.4	1.00	
<19	37.6	0.66 (0.33–1.29)	0.221
Regular exercise			
Yes	20.2	1.00	
No	79.8	1.50 (0.62–3.60)	0.367
Marital status			
Married	56.4	1.00	
Not married	43.3	1.20 (0.65–2.21)	0.568
Sleep duration			
≥5 h	56.4	1.00	
<5 h	43.3	2.75 (1.24–6.10)	0.013
Experience in current job			
≥1 yr	90.6	1.00	
<1 yr	9.4	1.32 (0.51–3.42)	0.569
Working hours per week			
Low	59.2	1.00	
High	40.8	0.89 (0.47–1.67)	0.715
Inadequate break time at work			
Not inadequate	45.6	1.00	
Inadequate	54.4	3.16 (1.50–6.66)	0.003
VDT			
Not VDT	75.3	1.00	
VDT	24.7	1.23 (0.62–2.42)	0.557
Finger repetition			
No	77.7	1.00	
Yes	22.3	1.09 (0.53–2.25)	0.811
Lifting			
No	47.4	1.00	
Yes	52.6	1.09 (0.59–2.03)	0.777
Driving			
No	64.5	1.00	
Yes	35.5	1.01 (0.53–1.91)	0.980
Standing			
No	43.1	1.00	
Yes	56.9	1.93 (0.98–3.80)	0.058
Work shift			
Regular shift	60.8	1.00	
Irregular shift	39.2	1.73 (0.94–3.21)	0.058
Job satisfaction			
Satisfied	43.4	1.00	
Not satisfied	56.6	1.38 (0.74–2.57)	0.310
Job control			
Controlled	46.4	1.00	
Not controlled	53.6	0.64 (0.35–1.19)	0.528
Worksite support			
Supported	91.3	1.00	
Not supported	8.7	1.15 (0.40–3.27)	0.800
Interpersonal stress at work			
Not stressed	51.2	1.00	
Stressed	48.8	1.93 (1.02–3.66)	0.045
Depressed mood with some issue at work			
Not feeling depressed	50.0	1.00	
Depressed	50.0	4.15 (1.89–9.07)	<0.001

CI: confidence interval.

Table 3. Adjusted odds ratios of risk factors which were significant for onset of severe Katakori

Risk factor	Adjusted odds ratio (95%CI)	p value
Gender		
Male	1.00	
Female	2.39 (1.18–4.86)	0.016
Sleep duration		
≥5 h	1.00	
<5 h	2.86 (1.20–6.82)	0.018
Depressed mood with some issue at work		
Not feeling depressed	1.00	
Depressed	3.11 (1.38–7.03)	0.006

CI: confidence interval.
Adjusted by gender, sleep duration and experience of depressed mood with some issue at work

in the follow-up period was 3.0% (42 workers), with mean (SD) age of 37.1 (9.0) years. Of those, 50% were males.

To assess the effect of the selected drop-out, the baseline characteristics of patients who were followed up (n=1,809) and those who dropped-out (n=842) are calculated. The mean (SD) age was 37.3 (10.0) years and 33.6 (8.5) years, respectively, and the majority were men in both groups (66.0% vs 57.7%). The prevalence of severe Katakori was 18.8% and 21.2%, respectively.

Crude odds ratios of baseline factors for onset of severe Katakori are shown in Table 2. The factors potentially relating to onset of severe Katakori were gender, visual fatigue, sleep duration, inadequate break time, standing, work shift, interpersonal stress and depressed mood with some issues at work. In psychosocial factors, depressed mood with some issues at work was only included, instead of interpersonal stress at work, because of its strong correlation (ρ= 0.4137, p<0.0001). The crude odds ratio of depressed mood with some issues at work was higher than the interpersonal stress at work, thus the higher factor was selected. Because 77% (281/366) of females were nurses, and 87% (255/294) of nurses were defined as irregular work shift, the correlation between female and irregular work shift was strong (ρ=0.3422, p<0.0001). Previous studies reported that Katakori was associated with females, so "female" was included in multivariate logistic regression analysis.

In the multivariate logistic regression analysis, these six factors were entered into the model. As a result, three potential risk factors were selected (Table 3).

A supplemental analysis was conducted to examine a combined impact of gender and nurses because 77% (281/366) were female nurses. We performed multivariate logistic regression analysis with the main three effects, nurse and interaction of gender and nurse. The adjusted odds ratios of main effects were similar to the main analysis, and the nurse effect as well as the interaction were not statistically significant. Based on these results, we propose three potential risk factors: gender, short sleep duration, and depressed mood with some issues at work which might associate with severe Katakori.

Discussion

To examine the association between onset of severe Katakori and potential risk factors, we conducted analyses using data from the CUPID study among urban workers in Japan. Although the incidence was small, severe Katakori occurred during the 1-year follow-up in some workers who had no or mild symptoms at baseline. A series of analyses showed gender, low sleep or depressed mood with some issues at work as important potential risk factors.

In our results, females showed higher odds (adjusted odds ratio=2.18) as a potential risk factor for onset of severe Katakori. According to the supplemental analysis, being female is potential risk factor of Katakori as it eliminates the possibility of nurses to affect the main result of this study. Based on these results, this study suggests the association of gender as a potential risk factor of severe Katakori. This finding is similar to those published previously[6, 8, 9]. We speculate this trend may be attributable to gender differences in muscle strength. Estrogen may also be involved in the pathogenesis of Katakori, although there is no scientific evidence for this assertion. Further studies will be required to explain the reason for gender differences in the manifestation of Katakori.

Being in a depressed frame of mind with some issues at work showed 3.1 times more increased risk of severe Katakori than those who are not. Previous cross-sectional studies suggest the association of Katakori and work stress, which was classified as a psychosocial factor[1, 6]. Krantz *et al.* have reported that emotional stress and psychologically stressful tasks are associated with increased electrographic activity in the trapezius muscle[13], and Hallman *et al.* have reported that autonomic imbalance is associated with neck shoulder pain, the Japanese definition of Katakori[14]. We suggest that psychosocial stress can progress to sympathetic and muscle stress, which may lead to the onset of Katakori.

In the present study, we found short sleep duration to be a potential risk factor. Mulligan *et al.* reported that nocturnal pain was associated with sleep quality, sleep duration, and habitual sleep efficiency in patients with shoulder disorders[15]. Short sleep duration might delay a daily recovery of tissue damage and cause the onset of severe Katakori. In order to ensure an adequate sleep duration, individuals should be responsible in attaining the required sleep duration, and support can be provided by encouraging a non-stressful work environment. In the present study, we had assessed sleep duration only. Further studies are required to explore any association between Katakori and the quality of sleep, including insomnia and other sleep disorders.

Factors identified as potential risk factors in the present study can be explained by Eriksen's hypothesis that head-down and neck flexion positions and/or psychological stress increase the intracellular nitric oxide/oxygen ratio through sympathetic nerve activity, resulting in inhibition of cytochrome oxidase; and then, lactate production would follow activating nociceptive fibers[16].

There were some limitations in this study. First, the generalizability of the findings may be limited. The majority of participants were male, and therefore a broad range of Japanese occupations was not represented. The study cohort was not a representative sample of the entire spectrum of Japanese workers in urban areas. Being female was one of the potential risk factors of Katakori although no interaction effects of gender and nurse were found in our supplemental analysis. However, the majority of females in this study were nurses, and the sample size included in the supplemental analysis may not have been sufficient. Therefore, our results need to be interpreted with care. Second, misclassification, to some extent, is inevitable. Information might be subjective in the decision of Katakori or sicknesses and missing value cannot be avoided due to the nature of a self-assessment survey. Third, drop-out may introduce bias into the data analysis due to the low follow-up rate of this study, although we considered that the baseline characteristics of both the follow-up group and the drop-out group seemed to be similar. Fourth, this study may not cover some unquestioned items which were not involved in the questionnaire. For example, some peculiar characteristics of Japanese may not be addressed by the original CUPID questionnaire regarding stress at work. Also, there were some items which were not involved in the original CUPID questionnaire as follows: disabilities of the arm, shoulder and hand questionnaire scores correlated significantly with depressive symptoms, catastrophic thinking, kinesiophobia, and pain anxiety[17]. The aforementioned behavioral items may need to be included as additional potential risk factors of severe Katakori. At last, a more complicated analysis model might be suitable for further assessment to discover other potential risk factors, instead of the logistic regression models assessed for the present analysis.

In conclusion, being female, short sleep duration and depressed mood with some issues at work were associated with onset of severe Katakori. We suggest that mental health support including the lack of sleep is important to prevent severe Katakori, especially for females.

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Research Paper

PAIN®

Classification of neck/shoulder pain in epidemiological research: a comparison of personal and occupational characteristics, disability, and prognosis among 12,195 workers from 18 countries

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Abstract

To inform case definition for neck/shoulder pain in epidemiological research, we compared levels of disability, patterns of association, and prognosis for pain that was limited to the neck or shoulders (LNSP) and more generalised musculoskeletal pain that involved the neck or shoulder(s) (GPNS). Baseline data on musculoskeletal pain, disability, and potential correlates were collected by questionnaire from 12,195 workers in 47 occupational groups (mostly office workers, nurses, and manual workers) in 18 countries (response rate = 70%). Continuing pain after a mean interval of 14 months was ascertained through a follow-up questionnaire in 9150 workers from 45 occupational groups. Associations with personal and occupational factors were assessed by Poisson regression and summarised by prevalence rate ratios (PRRs). The 1-month prevalence of GPNS at baseline was much greater than that of LNSP (35.1% vs 5.6%), and it tended to be more troublesome and disabling. Unlike LNSP, the prevalence of GPNS increased with age. Moreover, it showed significantly stronger associations with somatising tendency (PRR 1.6 vs 1.3) and poor mental health (PRR 1.3 vs 1.1); greater variation between the occupational groups studied (prevalence ranging from 0% to 67.6%) that correlated poorly with the variation in LNSP; and was more persistent at follow-up (72.1% vs 61.7%). Our findings highlight important epidemiological distinctions between subcategories of neck/shoulder pain. In future epidemiological research that bases case definitions on symptoms, it would be useful to distinguish pain that is localised to the neck or shoulder from more generalised pain that happens to involve the neck/shoulder region.

Keywords: Neck pain, Shoulder pain, Diagnostic classification, Case definition, Disability, Associations, Prognosis

1. Introduction

Pain in the neck and/or shoulder(s) is a common problem in people of working age and an important cause of disability. Like other regional pain, it may arise from identifiable musculoskeletal pathology—for example, cervical spondylitis or subacromial bursitis. However, the relationship of such abnormalities to symptoms is imperfect,[17] and their occurrence in association with pain does not necessarily imply that they are responsible for it. Furthermore, some modes of investigation that might be used to detect relevant pathology, in particular, magnetic resonance imaging, are relatively expensive and not readily applicable in large surveys. Most epidemiological studies of neck and shoulder pain have therefore defined cases by the occurrence and characteristics of symptoms. Moreover, because neck/shoulder pain can be difficult for patients to localise precisely and commonly extends across both the neck and shoulders, it has often been treated as a single diagnostic entity. Using this approach, it has been linked with occupational physical activities such as manual materials handling,[20] awkward postures,[2,20,24] and use of computers[28]; psychological factors such as low mood[8] and tendency to somatise[15]; and various psychosocial aspects of work.[16,21,24]

The merits of aggregating all pain in the neck and shoulder region will depend on whether there are identifiable subsets of cases that differ importantly in their causes, prognosis, or response to treatment.[4] For example, pain in the neck/shoulder is often accompanied by pain at other anatomical sites.[1,13,14,25] Pain that is localised only to the neck or shoulder might be more reflective of local pathology, whereas some psychological factors might show stronger associations with pain, which, although involving the neck or shoulder, is more widespread. If such distinctions occur, then associations with causes and effects of treatment may be diluted when all cases are aggregated.

The Cultural and Psychological Influences on Disability (CUPID) study is a large international investigation in which information about musculoskeletal pain, associated disability, and potential risk factors was collected from workers employed in 47 occupational groups distributed across 18 countries.[5] To explore whether there are differences between subcategories of neck/shoulder pain in associations and/or prognosis, we analysed data from the CUPID study, focusing in particular on pain that was limited to the neck or shoulder as compared with more generalised musculoskeletal pain that involved the neck or shoulder but also affected other anatomical sites. As well as comparing associations with demographic, physical, psychological, and psychosocial factors, we examined differences between the subcategories of pain in their relative prevalence by occupational group.

2. Methods

During 2006 to 2011, baseline information was collected by questionnaire from 47 occupational groups in 18 countries. Participants were aged 20 to 59 years and had been employed in their current job for at least 12 months. The occupational groups fell into 3 broad categories—nurses, office workers, and other workers (mostly performing manual tasks with their arms). In most groups, potentially eligible subjects were identified from employers' records, in some cases with random sampling to achieve the desired sample size (at least 200 per group if possible). The number of participants by group (mean response rate = 70%, response rate >80% in 33 of the 47 groups) varied from 92 to 1018, giving a total sample size of 12,426.

The questionnaire, which was completed either by self-administration or at interview, was originally drafted in English and then translated into local languages where necessary, with independent back-translation to ensure accuracy. Among other things, it covered demographic characteristics (sex and age), occupational activities (in an average working day), psychosocial aspects of work, somatising tendency, mental health, beliefs about arm pain, and experience of musculoskeletal pain and associated disability.

Somatising tendency was assessed through questions taken from the Brief Symptom Inventory[9] and was classified according to the number of symptoms from a total of five (faintness or dizziness, pains in the heart or chest, nausea or upset stomach, trouble getting breath, and hot or cold spells) that had been at least moderately distressing during the past week. Mental health was ascertained using elements from the Short Form-36 questionnaire[29] and was graded to 3 levels (good, intermediate, and poor) representing approximate thirds of the distribution of scores in the full study sample. Questions on beliefs about arm pain were adapted from the Fear Avoidance Beliefs Questionnaire.[27] Participants were classed as having adverse beliefs about the work-relatedness of arm pain if they completely agreed that such pain is commonly caused by work; about the impact of physical activity if they completely agreed that for someone with such pain, physical activity should be avoided as it might cause harm, and that rest is needed to get better; and about its prognosis if they completely agreed that neglecting such problems can cause serious harm and completely disagreed that such problems usually get better within 3 months.

The questions about musculoskeletal pain concerned 10 anatomical sites (low back; neck; and left and right shoulder, elbow, wrist/hand, and knee), which were illustrated with body mannequins. For each site, participants were asked whether they had experienced pain that had lasted for longer than a day (1) during the past 12 months and (2) during the past month. Pain in

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the neck or shoulder was classed as disabling if it had made it difficult or impossible to get dressed, do normal jobs around the house, or (for shoulder only) comb/brush hair or bath/shower.

Approximately 14 months after baseline, participants from 45 occupational groups who had given consent were asked to complete a shorter follow-up questionnaire, which used identical questions to ascertain experience of musculoskeletal pain in the past month. Follow-up was not possible for office workers in South Africa or for manual workers in Costa Rica. Further details of the methods of data collection in the CUPID study have been reported elsewhere.[5]

Statistical analysis was performed with Stata version 12.1 software (Stata Corp LP, College Station, TX) and focused on the 1-month prevalence at baseline of 2 main categories of pain: localised neck/shoulder pain (LNSP) and generalised pain involving the neck or shoulder(s) (GPNS). The former was defined as pain in the neck and/or shoulder(s) with no pain at any of the other 7 anatomical sites during the past 12 months. Neck or shoulder pain during the past month that occurred in a context of pain at one or more other anatomical sites during the past 12 months was classed as GPNS. Within the category of LNSP, we further distinguished 2 subsets of cases—those in whom all pain in the past 12 months was restricted to the neck (localised neck pain) and those in whom all pain in the past 12 months was limited to one or both shoulders (localised shoulder pain).

We first used simple descriptive statistics to describe the frequency and severity of different pain outcomes at baseline. Next, we applied Poisson regression with confidence intervals (CIs) based on robust SEs to assess the cross-sectional association of various personal and occupational factors with each of LNSP, GPNS, localised neck pain, and localised shoulder pain. In each analysis, the measure of pain was taken as the outcome variable, and the comparison group was people with no pain in either the neck or shoulders in the past 12 months. To account for possible clustering by occupational group, we used hierarchical, random intercept modelling, associations being summarised by prevalence rate ratios (PRRs). To assess the significance of differences in associations for LNSP and GPNS, we performed a further Poisson regression analysis with GPNS as the outcome and LNSP as the comparator. Similarly, the significance of differences in associations with localised neck as compared with localised shoulder pain was assessed through a model with localised neck pain as the outcome and localised shoulder pain as the comparator.

We then examined the prevalence of LNSP and GPNS by occupational group and their correlation after adjustment for other factors. To derive adjusted prevalence rates, we first took no neck/shoulder pain in the past 12 months as a comparator and estimated PRRs for LNSP and GPNS in each occupational group relative to a reference (office workers in the United Kingdom), using Poisson regression models that included the other factors. Next, we calculated the "adjusted numbers" of participants in each occupational group with the 2 pain outcomes that would give crude PRRs equal to those estimated from the regression model. We then used these adjusted numbers to calculate adjusted prevalence rates.

Finally, we explored the prevalence of continuing pain in the month preceding follow-up for different categories of neck/shoulder pain at baseline.

Ethical approval for the study was provided by the relevant research ethics committee in each participating country.[5]

3. Results

One hundred ninety of the 12,426 participants were excluded from the analysis because of missing information about pain in the neck or shoulders in the past month and/or 12 months, together with a further 41 participants who provided incomplete data on pain at other anatomical sites in the past 12 months. Among the remaining 12,195 subjects, 4241 (35%) were men.

Table 1 shows the 1-month prevalence and severity of different categories of neck/shoulder pain at baseline. Overall, neck/shoulder pain in the past month was common (40.7%) and occurred mostly in a context of more widespread pain in the past 12 months (prevalence = 35.1%). In contrast, the prevalence of pain that was localised to the neck and/or shoulders was lower (5.6%) and particularly that of pain which was limited entirely to the shoulders (1.2%). Most of the latter was restricted to a single

Table 1

One-month prevalence and severity of different categories of neck/shoulder pain.

Category of pain	Definition	Number of cases*	Prevalence percent (95% CI)	Proportion percent (95% CI) of cases in which pain			
				Was present for >14 d in the past month	Was disabling in the past month	Led to medical consultation in the past 12 mo	Caused absence from work in the past 12 mo
Localised neck pain	Pain in neck in the past month, no pain elsewhere in the past 12 mo	302	2.5 (2.2-2.8)	18.5 (14.3-23.4)	23.8 (19.1-29.1)	35.1 (29.7-40.8)	10.9 (7.6-15.0)
Localised shoulder pain	Pain in 1 or both shoulders in the past month, no pain elsewhere in the past 12 mo	152	1.2 (1.1-1.5)	22.4 (16.0-29.8)	48.0 (39.9-56.3)	28.9 (21.9-36.8)	12.5 (7.8-18.8)
Localised neck/ shoulder pain	Pain in neck and/or shoulder(s) in the past month, no pain elsewhere in the past 12 mo	680	5.6 (5.2-6.0)	24.0 (20.8-27.4)	35.6 (32.0-39.3)	38.2 (34.6-42.0)	11.3 (9.0-13.9)
Generalised pain involving neck/ shoulder	Pain in neck and/or shoulders in the past month, with pain at other sites in the past 12 mo	4282	35.1 (34.3-36.0)	30.5 (29.1-31.9)	56.9 (55.4-58.4)	49.1 (47.6-50.6)	20.3 (19.1-21.6)

* In addition, 5344 participants had no neck or shoulder pain in the past 12 months, and 1889 had neck and/or shoulder pain in the past 12 months, but not in the past month.

shoulder (122 of the 152 cases). Most participants with GPNS (93%) reported pain in the past 12 months in the low back and/or knees as well as any pain in the upper limb. Generalised pain involving the neck or shoulder(s) tended to be more troublesome and disabling than LNSP. For example, it had made everyday activities difficult or impossible during the past month in 56.9% of cases as compared with 35.6% of those with LNSP; and it had caused absence from work during the past year in 20.3% of cases as compared with 11.3% of those in whom the pain was localised. When the analysis was repeated separately for 8 strata of sex and age, the patterns were similar across each stratum.

Table 2 shows baseline associations with personal and occupational factors separately for LNSP and GPNS, in comparison with no pain in the neck or shoulders in the past 12 months. Both categories of pain were significantly more frequent in women than in men (PRRs of 1.4 and 1.3, respectively), and both were associated with a tendency to somatise. However, the relationship to somatising tendency was stronger for GPNS (PRR 1.6, 95% CI 1.5-1.8, for report of distress from 2 or more somatic symptoms compared to none, P for trend <0.001) than for LNSP (PRR 1.3, 95% CI 1.1-1.5, for report of distress from 2 or more somatic symptoms compared to none, P for trend <0.001). Generalised pain involving the neck or shoulder(s) also showed a stronger association with poor mental health, and unlike LNSP, its prevalence increased significantly with age. Direct comparison of the 2 pain outcomes (in a single Poisson regression model that effectively took those with GPNS as cases and those with LNSP as controls) indicated that the differences in associations with age, somatising tendency, and mental health were statistically significant ($P < 0.05$). In addition, both categories of neck/shoulder pain were more weakly linked with prolonged use of keyboards at work (PRR 1.3 for LNSP and 1.1 for GPNS) and adverse beliefs about the prognosis of arm pain (PRRs 1.3 and 1.1, respectively); and GPNS with occupational lifting, work with the hands above shoulder height and adverse beliefs about the work-relatedness of arm pain.

Table 3 presents corresponding risk estimates for localised neck pain and localised shoulder pain, defined as in **Table 1** (again the comparator was no pain in the neck or shoulders in the past 12 months). There were clear differences in the patterns of association, such that the prevalence of localised neck pain was markedly higher in women than in men (PRR 1.7, 95% CI 1.2-2.3), lower at older ages (P for linear trend across age categories $=$ 0.04), and significantly associated with somatising tendency, lack of support at work, job insecurity, and particularly use of a keyboard for >4 hours in an average working day (PRR 1.9,

Table 2

Associations of neck/shoulder pain with personal and occupational factors.

Personal/occupational factor	Localised neck/shoulder pain			Generalised pain involving the neck/shoulder		
	Number of cases (%)	PRR*	95% CI	Number of cases (%)	PRR*	95% CI
Sex						
Male	211 (7.9)	1		1009 (29.1)	1	
Female	469 (14.0)	1.4	1.1-1.7	3273 (53.1)	1.3	1.2-1.4
Age, y						
20-29	180 (10.6)	1		856 (36.0)	1	
30-39	230 (11.8)	1.1	0.9-1.4	1329 (43.6)	1.2	1.1-1.3
40-49	193 (12.5)	1.1	0.9-1.4	1327 (49.6)	1.3	1.1-1.4
50-59	77 (9.3)	0.8	0.7-1.1	770 (50.7)	1.3	1.2-1.5
Activity in an average working day						
Lifting weights ≥25 kg	199 (9.4)	0.9	0.7-1.1	1602 (45.5)	1.1	1.0-1.1
Working with hands above shoulder height for >1 h	177 (10.3)	1.0	0.9-1.3	1508 (49.4)	1.1	1.1-1.2
Use of keyboard for >4 h	316 (15.6)	1.3	1.1-1.6	1725 (50.2)	1.1	1.0-1.2
Psychosocial aspects of work						
Work for >50 h per week	140 (8.2)	1.0	0.7-1.2	592 (27.5)	0.9	0.8-1.0
Time pressure at work	485 (10.9)	1.1	0.9-1.3	3350 (45.9)	1.2	1.1-1.2
Incentives at work	188 (10.5)	1.0	0.9-1.2	1140 (41.5)	0.9	0.9-1.0
Lack of support at work	174 (15.4)	1.1	0.9-1.4	1344 (58.5)	1.1	1.0-1.1
Job dissatisfaction	146 (11.7)	1.1	0.9-1.4	868 (43.9)	1.0	1.0-1.1
Lack of job control	130 (10.3)	1.0	0.8-1.2	963 (46.0)	1.0	0.9-1.1
Job insecurity	195 (10.0)	1.0	0.9-1.1	1331 (43.2)	1.0	1.0-1.1
Number of distressing somatic symptoms in the past week						
0	425 (9.9)	1		1859 (32.4)	1	
1	163 (15.1)	1.3	1.1-1.6	1059 (53.6)	1.4	1.3-1.5
2+	87 (14.8)	1.3	1.1-1.5	1320 (72.4)	1.6	1.5-1.8
Missing	5 (9.6)	1.0	0.3-3.0	44 (48.4)	1.3	1.1-1.6
Mental health						
Good	265 (10.4)	1		1311 (36.4)	1	
Intermediate	216 (12.3)	1.2	0.9-1.4	1333 (46.3)	1.2	1.1-1.3
Poor	195 (11.7)	1.1	0.9-1.4	1621 (52.5)	1.3	1.2-1.4
Missing	4 (9.3)	1.1	0.5-2.5	17 (30.4)	0.8	0.5,1.1
Adverse beliefs about arm pain						
Work-relatedness	159 (11.4)	1.1	0.9-1.3	1613 (56.6)	1.2	1.2-1.3
Physical activity	62 (8.7)	0.8	0.6-1.0	425 (39.5)	0.8	0.8-0.9
Prognosis	69 (15.2)	1.3	1.0-1.5	604 (61.0)	1.1	1.1-1.2

The denominators for percentages of cases are the total numbers of cases and referents with the relevant personal/occupational factor.

* Prevalence rate ratios (PRRs) derived from a single Poisson regression model, with random intercept modelling to allow for clustering by occupational group. The reference group was participants with no pain in the neck or shoulders in the past 12 months (n = 5344).

Table 3

Associations of localised neck pain and localised shoulder pain with personal and occupational factors.

Personal/occuptional factor	Localised neck pain			Localised shoulder pain		
	Number of cases (%)	PRR*	95% CI	Number of cases (%)	PRR*	95% CI
Sex						
Male	85 (3.3)	1		58 (2.3)	1	
Female	217 (7.0)	1.7	1.2-2.3	94 (3.2)	1.3	0.9-1.8
Age, y						
20-29	96 (5.9)	1		39 (2.5)	1	
30-39	104 (5.7)	1.0	0.8-1.3	44 (2.5)	1.0	0.7-1.5
40-49	76 (5.3)	0.9	0.7-1.2	46 (3.3)	1.3	0.8-2.0
50-59	26 (3.4)	0.6	0.3-1.0	23 (3.0)	1.2	0.7-1.8
Activity in an average working day						
Lifting weights ≥25 kg	96 (4.8)	0.9	0.6-1.3	42 (2.1)	0.7	0.5-1.2
Working with hands above shoulder height for >1 h	82 (5.0)	1.0	0.8-1.3	50 (3.1)	1.3	1.0-1.8
Use of keyboard for >4 h	155 (8.3)	1.9	1.5-2.4	53 (3.0)	1.0	0.7-1.4
Psychosocial aspects of work						
Work for >50 h per wk	71 (4.3)	1.2	0.8-1.8	35 (2.2)	0.9	0.5-1.5
Time pressure at work	215 (5.2)	1.0	0.7-1.2	117 (2.9)	1.3	0.9-2.0
Incentives at work	92 (5.4)	1.2	0.9-1.5	40 (2.4)	0.8	0.5-1.2
Lack of support at work	92 (8.8)	1.5	1.1-2.0	21 (2.2)	0.7	0.4-1.1
Job dissatisfaction	63 (5.4)	1.1	0.8-1.3	34 (3.0)	1.3	0.9-2.0
Lack of job control	49 (4.2)	0.7	0.6-0.9	33 (2.8)	1.1	0.7-1.7
Job insecurity	104 (5.6)	1.2	1.0-1.5	43 (2.4)	0.9	0.6-1.2
Number of distressing somatic symptoms in the past week						
0	179 (4.4)	1		102 (2.6)	1	
1	77 (7.7)	1.5	1.1-2.0	28 (3.0)	1.0	0.7-1.5
2+	45 (8.2)	1.5	1.1-2.1	18 (3.5)	1.2	0.7-2.0
Missing	1 (2.1)	1	0.1-7.7	4 (7.8)	2.2	0.7-6.8
Mental health						
Good	117 (4.9)	1		56 (2.4)	1	
Intermediate	98 (6.0)	1.2	0.9-1.5	50 (3.1)	1.3	0.8-2.1
Poor	87 (5.6)	1.1	0.9-1.5	43 (2.8)	1.3	0.8-2.1
Missing	0 (0)	0.0	0.0-0.0	3 (7.1)	1.8	0.6-5.3
Adverse beliefs about arm pain						
Work-relatedness	66 (5.1)	0.9	0.7-1.3	38 (3.0)	1.1	0.8-1.5
Physical activity	28 (4.1)	0.8	0.5-1.2	20 (3.0)	1.1	0.7-1.8
Prognosis	23 (5.6)	0.9	0.7-1.3	15 (3.7)	1.4	1.0-2.1

The denominators for percentages of cases are the total numbers of cases and referents with the relevant personal/occupational factor.

* Prevalence rate ratios (PRRs) derived from a single Poisson regression model, with random intercept modelling to allow for clustering by occupational group. The reference group was participants with no pain in the neck or shoulders in the past 12 months (n = 5344).

95% CI 1.5-2.4). In contrast, localised shoulder pain was associated with work with the hands above shoulder height (PRR 1.3, 95% CI 1.0-1.8) and belief that arm pain has a poor prognosis (PRR 1.4, 95% CI 1.0-2.1). Direct comparison of localised neck pain with localised shoulder pain indicated that the differences in associations with age, use of a keyboard, and lack of support at work were statistically significant ($P < 0.05$).

Figure 1 summarises the crude prevalence of LNSP and GPNS across the 47 occupational groups. In almost all groups, GPNS predominated. Rates for LNSP ranged from 0.5% among flower plantation workers in Ecuador and 1.1% in Colombian office workers to 11.2% and 11.8% in office workers from Spain and Sri Lanka, respectively. For GPNS, the variation between occupational groups was even greater with zero prevalence among sugar cane cutters in Brazil and a rate as high as 67.6% in Costa Rican telephone call centre workers. Office workers tended to have higher prevalence of LNSP than nurses, but there were no consistent differences in GPNS by type of occupation. The proportion of neck/shoulder pain that was localised did not relate consistently to its overall prevalence.

Figure 2 plots the prevalence of LNSP by occupational group against that for GPNS, after adjustment for the factors listed in **Table 2**. After such adjustment, the variation in GPNS was a little reduced, and there was little correlation between the 2 types of pain (Spearman correlation coefficient = 0.22 overall, 0.46 in nurses, -0.47 in office workers and 0.45 in other workers).

Follow-up data were sought for 45 of the 47 occupational groups, and among the 11,764 participants in these groups, 9150 (78%) provided satisfactory information about neck and shoulder pain after a mean interval of 14 months (range 3-35 months, 84% within 11-19 months) from baseline. **Table 4** shows the prevalence of continuing pain at follow-up for different categories of neck/shoulder pain at baseline. The persistence of neck/shoulder pain was significantly higher ($P = 0.003$) when it was associated with pain at other anatomical sites in the past year (72.1%) than when it was localised (61.7%). Persistence was lowest for pain that was localised to the shoulders, with a prevalence of 31.9% for pain in the shoulder(s) during the month before follow-up and 41.6% for pain in the neck or shoulders.

4. Discussion

Our findings indicate that most neck and shoulder pain occurs in a context of current or recent pain at other anatomical sites, and that in these circumstances, it tends to be more troublesome and disabling than pain that is localised entirely to the neck/shoulder

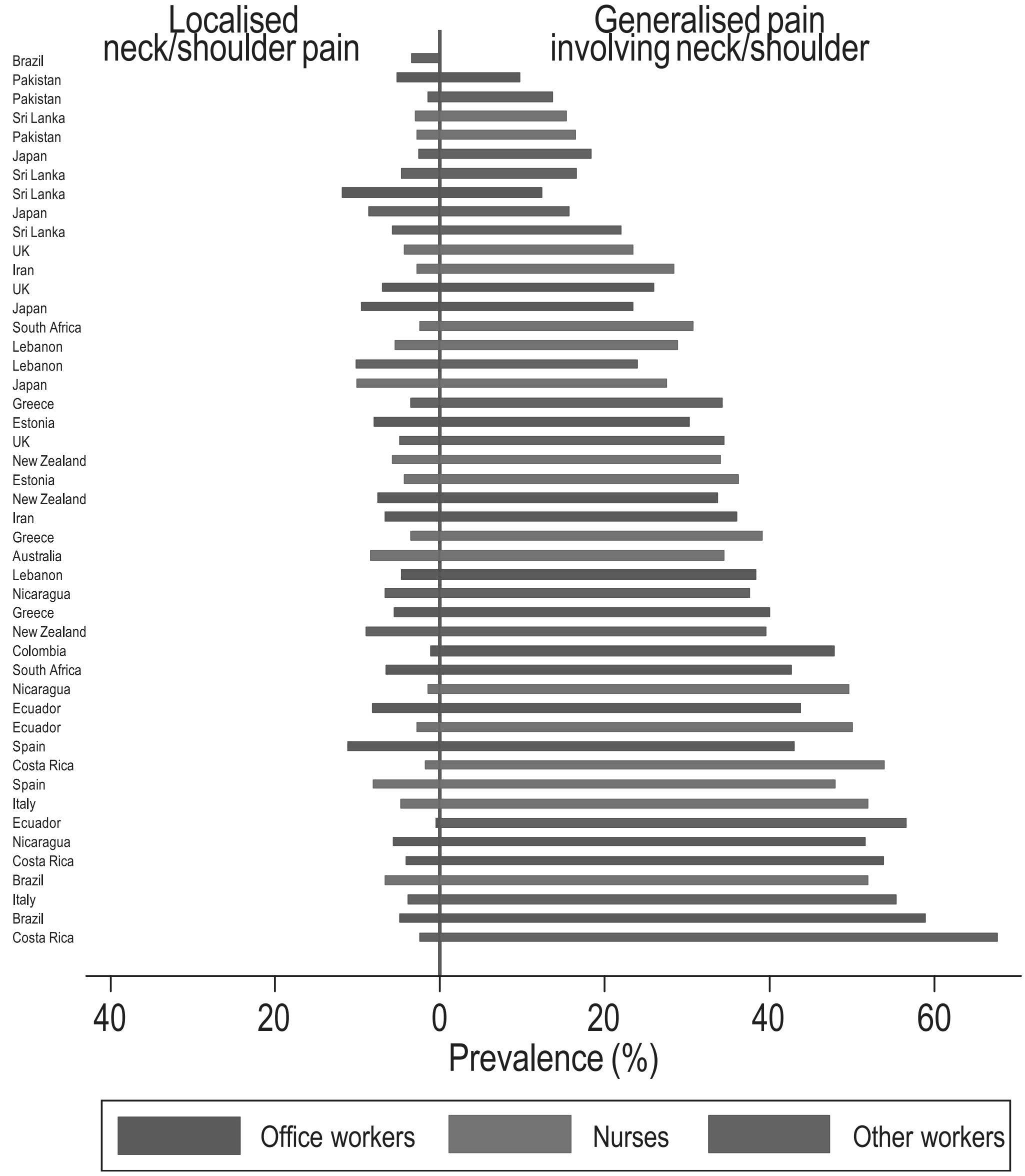

Figure 1. Crude 1-month prevalence of localised neck–shoulder pain and generalised pain involving neck/shoulder by occupational group.

area. Furthermore, it seems that these 2 subcategories of neck/shoulder pain differ importantly in their epidemiology. Thus, GPNS showed stronger associations with somatising tendency, poor mental health and older age, greater variation between the occupational groups studied (which correlated poorly with the variation in LNSP), and tended to be more persistent. There were also differences between pain that was localised to the neck and that which was localised to one or both the shoulders, the former being less frequent at older ages and strongly associated with prolonged use of keyboards at work.

Several earlier reports have described the occurrence and determinants of neck/shoulder pain in specific occupational groups from the CUPID study in Australia,[15] Brazil and Italy,[3] Estonia,[10,22] Iran,[26] Japan,[19] New Zealand,[11,12] and Sri Lanka.[30] However, the much larger size of the current analysis made it possible to examine diagnostic subgroups in a way that could not be done meaningfully with smaller data sets. It also enabled comparison of prevalence rates across a large number of occupational groups in a diversity of countries.

Information was collected through a standardised questionnaire, and while in some occupational groups, interviews were used as an alternative to self-administration, there is no reason to expect that this would have differentially affected the reporting of localised neck/shoulder pain as compared with pain that was more generalised. Translation of the questionnaire into local languages was checked by independent back-translation, and errors in reporting should have been further reduced by the use of pictures to define the anatomical areas of interest. In the cross-sectional analyses for **Tables 2 and 3**, there was a possibility of bias if experience of pain modified recall of occupational exposures, and also of reverse causation if, for example, neck/shoulder pain led to greater awareness of somatic symptoms. Moreover, the prevalence of pain may have been reduced through healthy worker selection. Again, however, there is no

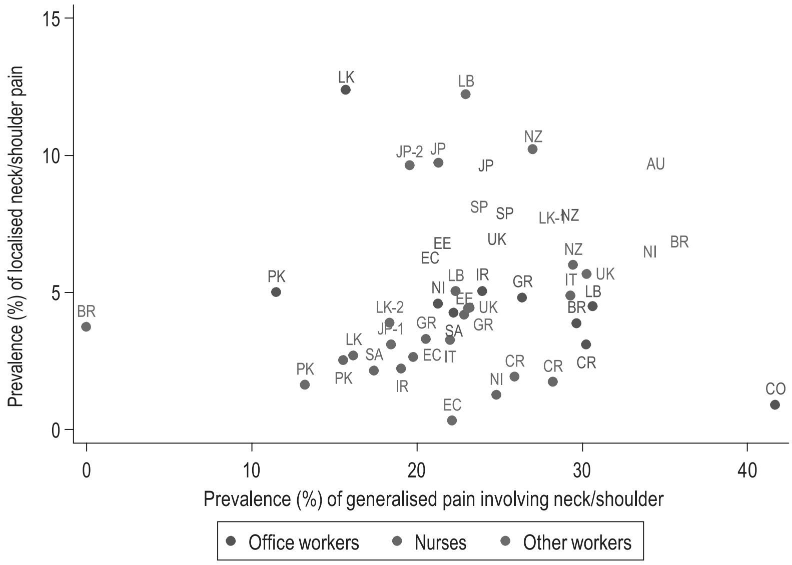

Figure 2. Adjusted 1-month prevalence of localised neck–shoulder pain and generalised pain involving neck/shoulder by occupational group. Prevalence rates are adjusted for all of the personal and occupational factors in Table 2 (See Section 2 on Methods). Key to countries: AU, Australia; BR, Brazil; CO, Colombia; CR, Costa Rica; EC, Ecuador; EE, Estonia; GR, Greece; IR, Iran; IT, Italy; JP, Japan; LB, Lebanon; LK, Sri Lanka; NI, Nicaragua; NZ, New Zealand; PK, Pakistan; SA, South Africa; SP, Spain; UK, United Kingdom.

reason to expect major differences in such effects according to whether pain was localised to the neck and shoulder or more generalised.

The criteria by which we distinguished between LNSP and GPNS were to some extent arbitrary. Subject to the limits of participants' recall, they ensured that those with LNSP had not suffered from pain at other anatomical sites in the 12 months before baseline. However, it remains possible that this group included some people with a predisposition to pain at multiple sites which would have become manifest had they been studied over a longer period. Nevertheless, the case definitions were adequate to reveal important differences in epidemiological features. Some GPNS may have reflected radiation to the distal arm of pain that arose from primary pathology in the neck, but most participants with GPNS (93%) reported pain in the past 12 months in the low back and/or knees as well as any pain in the upper limb.

Several previous studies have documented the frequent co-occurrence of neck and shoulder pain[24] and also their association with pain in the lower back and at other anatomical sites.[8,18,21] However, we have been unable to identify any investigations that focused on pain limited only to the neck or shoulders.

Studies that have examined neck pain overall have found higher rates in women than in men[21,23] and at older ages.[21] This is consistent with our findings for GPNS (which included most of the participants with neck pain in the past month at baseline). Moreover, pain that was localised entirely to the neck showed an even greater difference by sex (PRR 1.7, 95% CI 1.2-2.3). However, in contrast to GPNS, localised neck pain was less prevalent at older ages.

Many studies have examined the relationship of neck and/or shoulder pain to physical activities at work, associations being found most consistently with manual material handling[20] and awkward postures,[2,20,24] including work with the hands above shoulder height,[20] and to a lesser extent with computer work.[28] We found that localised neck pain was more prevalent among participants who reported prolonged use of computer keyboards (PRR 1.9, 95% CI 1.5-2.4) and a borderline association of localised shoulder pain with prolonged elevation of the arms at work, but otherwise there were no clear relationships with physical activities for any of the pain outcomes examined. This may have been because within each occupational group, exposures to physical activities were fairly homogeneous, making

Table 4

One-month prevalence of pain in neck and/or shoulders at follow-up by category of neck/shoulder pain at baseline.

Category of pain at baseline	Number of cases eligible for follow-up	Number of cases (%) who completed follow-up	Number (%)* of cases with pain at the same site in the past month at follow-up			Number (%)* of cases with pain in neck and/or shoulder(s) in the past month at follow-up		
			Number of cases	Percentage*	95% CI	Number of cases	Percentage*	95% CI
Localised neck pain	289	219 (75.8)	123	56.2	49.3-62.8	137	62.6	55.8-69.0
Localised shoulder pain	148	113 (76.4)	36	31.9	23.4-41.3	47	41.6	32.4-51.2
Localised neck/shoulder pain	660	501 (75.9)				309	61.7	57.3-66.0
Generalised pain involving neck/shoulder	4047	3253 (80.4)				2344	72.1	70.5-73.6

Analysis was restricted to the 9150 cases with satisfactory information about neck/shoulder pain at follow-up.
* Percentage of those who completed follow-up.

it difficult to detect effects in analyses that adjusted for occupational group.

Homogeneity of exposures within occupational groups may also have limited our ability to discriminate associations with psychosocial aspects of work, which again have been implicated previously in the occurrence of neck and shoulder pain,[16,21,24] although mostly with estimates of relative risk less than 2.[16] It was not possible to identify any clear differences between LNSP and GPNS, and although lack of support at work carried a higher risk of localised neck pain (PRR 1.5, 95% CI 1.1-2.0), this may have been a chance observation in the context of multiple testing.

In contrast, stronger associations were observed with somatising tendency and poor mental health. For poor mental health, which has been linked previously with neck pain,[28] the relationship was limited to GPNS, whereas for somatising tendency, it extended to localised pain but was stronger for GPNS (PRR for ≥2 vs 0 distressing somatic symptoms 1.6, 95% CI 1.5-1.8). The last finding is consistent with the earlier observation that within the CUPID study, somatising tendency is associated particularly with multisite musculoskeletal pain.[7] It might be expected that people who are prone to worry about other common somatic symptoms would also be more aware of musculoskeletal pain and more likely to report it. The weaker relationship to localised pain in the shoulder(s) suggests that the latter may be determined more by localised factors (eg, pathology in the shoulder or health beliefs relating specifically to the shoulder).

The association that we observed between localised shoulder pain and adverse beliefs about the prognosis of arm pain (PRR 1.4 95% CI 1.0-2.1) may reflect a relationship more to the persistence than the incidence of symptoms. Prevalence depends on both incidence and persistence, and our cross-sectional analysis could not distinguish between effects on one as compared with the other.

We also found marked differences in the prevalence of neck/shoulder pain by occupational group and in the proportion of such pain that was localised to the neck/shoulder region (evidenced by the absence of clear positive correlation between the 2 categories of pain in **Figure 1**). The larger variation was for GPNS and tended to parallel that reported previously for disabling pain in the low back and wrist/hand regions.[6] This may be because, like neck/shoulder pain, most low back and wrist/hand pain occurs in people with a high susceptibility to musculoskeletal pain in general. The differences were somewhat reduced after control for known and suspected risk factors, but remained large. They might in part reflect differences in understanding of pain, across different cultures and especially between populations speaking different languages. However, such differences could not explain the variation between occupational groups in the proportion of neck/shoulder pain that was localised, which again was marked. The lack of correlation between the prevalence of LNSP and GPNS suggests differences in general predisposition to complain of musculoskeletal pain, perhaps culturally determined, that are not explained by differences in somatising tendency or other known or suspected risk factors for such pain. Whatever the explanation, the differential variation adds to the case for treating LNSP and GPNS as separate entities.

That case is further supported by the observation that in comparison with LNSP, GPNS tended to be more persistent at follow-up. This pattern would be expected if the general predisposition to pain that seems to drive rates of GPNS were a fairly unchanging personal characteristic, whereas LNSP was more influenced by transient factors such as reversible injuries to local tissues in the neck and shoulders.

In conclusion, our findings point to important distinctions between subcategories of neck/shoulder pain. It is uncommon for people with neck/shoulder pain not to have experienced pain also at other anatomical sites during the past year and those whose pain is limited to the neck and/or shoulders tend to be younger, to somatise less, and to be less disabled by their pain. Localised neck/shoulder pain is also less persistent than that which is associated with pain elsewhere and shows stronger associations with occupational physical activities, perhaps reflecting specific effects on local tissues (eg, muscle fatigue from postures associated with prolonged use of keyboards). In future research on neck/shoulder pain that bases case definitions only on symptoms, it would be useful to distinguish pain that is localised to the neck or shoulder from more generalised pain that happens to involve the neck/shoulder region as well as other parts of the body.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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Prevalence of radiographic hip osteoarthritis and its association with hip pain in Japanese men and women: the ROAD study

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Objective: Although hip osteoarthritis (OA) is a major cause of hip pain and disability in elderly people, few epidemiologic studies have been performed. We investigated the prevalence of radiographic hip OA and its association with hip pain in Japanese men and women using a large-scale population of a nationwide cohort study, Research on Osteoarthritis/osteoporosis Against Disability (ROAD).

Methods: From the baseline survey of the ROAD study, 2975 participants (1043 men and 1932 women), aged 23–94 years (mean 70.2 years), living in urban, mountainous, and coastal communities were analyzed. The radiographic severity at both hips was determined by the Kellgren/Lawrence (K/L) grading system. Radiographic hip OA was defined as K/L $\geq$ 2, and severe radiographic hip OA as K/L $\geq$ 3.

Results: The crude prevalence of radiographic hip OA was 18.2% and 14.3% in men and women, respectively, that of severe radiographic hip OA was 1.34% and 2.54%, and that of symptomatic K/L $\geq$ 2 OA was 0.29% and 0.99%, respectively. The crude prevalence of hip OA, including severe OA, was not age-dependent in men or women. Male sex was a risk factor for radiographic hip OA, whereas female sex was a risk factor for severe radiographic hip OA and hip pain. Compared with K/L = 0/1, hip pain was significantly associated with K/L $\geq$ 3, but not with K/L = 2.

Conclusion: The present cross-sectional study revealed the prevalence of radiographic hip OA and severe hip OA in Japanese men and women. Hip pain was strongly associated with K/L $\geq$ 3.

Introduction

Hip osteoarthritis (OA) is a major public health issue causing chronic disability of elderly people in most developed countries[1,2]. Despite the urgent need for strategies to prevent and treat this condition, epidemiologic data on hip OA are sparse. The reported prevalence of radiographic hip OA differs considerably among previous population-based epidemiologic studies[1,3–8]. This may be due to limitations in sample size or variability in age, ethnicity, and radiologic acquisition. In particular, previous studies suggested that the prevalence of OA at other sites, such as the knee, differed among races. In addition, anthropometric measurements and environmental situations vary substantially in different countries. Thus findings in Caucasians cannot be applied to different ethnic groups. In Japan, our previous study in 1998 was the only population-based study to examine the prevalence of hip OA. With the aging population, there have been dramatic changes in number of elderly people; this aging may have affected the prevalence of hip OA. To the best of our knowledge, no population-based cohort studies for hip OA have been performed in Japan since our previous study.

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Hip pain is the principal clinical symptom of hip OA[9], but the reported prevalence of hip pain and symptomatic hip OA also differs among previous population-based epidemiologic studies[1,5–8]. In addition the impact of hip OA on pain remains controversial.

With the goal of establishing epidemiologic indices to evaluate clinical evidence for the development of disease-modifying treatment, we set up a large-scale nationwide cohort study for bone and joint disease called ROAD (Research on Osteoarthritis/osteoporosis Against Disability) in 2005. We have to date created a baseline database with detailed clinical and genetic information on three population-based cohorts in urban, mountainous, and coastal communities of Japan.

The objective of this study was to examine the prevalence of radiographic hip OA as well as hip pain and symptomatic hip OA by gender and age strata in Japanese men and women in a large-scale, population-based cohort from the ROAD study. We also examined the association of the severity of hip OA with the presence of hip pain.

Subjects and methods

The ROAD study is a nationwide prospective study of bone and joint diseases (with osteoarthritis and osteoporosis as the representative bone and joint diseases) constituting population-based cohorts established in several communities in Japan. As a detailed profile of the ROAD study has already been described elsewhere[10–12], a brief summary is provided here. From 2005 to 2007, we created a baseline database that included clinical and genetic information for 3040 inhabitants (1061 men, 1979 women) in the age range of 23–95 years (mean 70.6 years), recruited from listings of resident registrations in three communities: an urban region in Itabashi, Tokyo, with a population of 529,400/32 km^2 with 0.1, 25, and 75% of jobs in the primary industry (agriculture, forestry, fishing, and mining), the secondary industry (manufacturing and construction), and the tertiary industry (service industry), respectively, and residents $\geq$65 years constituted 19.1% of the population; a mountainous region in Hidakagawa, Wakayama, with a population of 11,300/330 km^2 with 29, 24, and 47% of jobs in the three industries above, and 30.5% were $\geq$65 years; and a coastal region in Taiji, Wakayama, with a population of 3500/6 km^2 with 13, 18, and 69% of jobs in the three industries, and those $\geq$65 years accounted for 34.9% of the total. Participants in the urban region were recruited from a cohort study[13] in which the participants were randomly drawn from the Itabashi-ward residents register database, and the response rate in the age groups of $\geq$60 years was 75.6%. Participants in the mountainous and coastal regions were recruited from listings of resident registration and the response rates in the age group of $\geq$40 years were 57.3% and 33.1%, respectively. However, those inhabitants aged <60 years in the urban region and <40 years in the mountainous and coastal regions who were interested in participating in the study were invited to be examined. The inclusion criteria, apart from residence in the communities mentioned above, were the ability to walk to the survey site, report data, and understand and sign an informed consent form. All participants provided written informed consent, and the study was conducted with the approval of the ethics committees of the University of Tokyo and the Tokyo Metropolitan Geriatric Medical Center.

Participants completed an interviewer-administered questionnaire of 400 items that included lifestyle information such as smoking habits, alcohol consumption, family history, medical history, and previous hip injury history. Anthropometric measurements included height and weight, from which the body mass index (BMI) (weight [kg]/height [m^2]) was calculated. Furthermore, all participants were interviewed by well-experienced orthopedists regarding pain in both hips, who asked "Have you experienced right hip pain on most days in the past month, in addition to now?" and "Have you experienced left hip pain on most days in the past month, in addition to now?" Subjects who answered "yes" were defined as having hip pain. We defined an individual as having hip pain if at least one of the hip joints was affected.

Radiographic assessment

All participants underwent radiographic examination of both hips using an anteroposterior view with weight-bearing and feet internally rotated. Fluoroscopic guidance with a horizontal anteroposterior X-ray beam was used to properly visualize the joint space. Hip radiographs at baseline were read without knowledge of the participant's clinical status by a single, well-experienced orthopedist (TI), and the Kellgren/Lawrence (K/L) grade was defined using the K/L radiographic atlas for overall hip radiographic grades[14]. In the K/L grading system, radiographs are scored from grade 0 to grade 4, with higher grades being associated with more severe OA. To evaluate intraobserver variability of K/L grading, 100 randomly selected radiographs of the hip were scored by the same observer more than 1 month after the first reading. One hundred other radiographs were also scored by two experienced orthopedic surgeons (TI and SM) using the same atlas for interobserver variability. The intra- and intervariabilities evaluated for K/L grade (0–4) were confirmed by kappa analysis to be sufficient for assessment ($\kappa = 0.87$ and $\kappa = 0.85$, respectively).

Radiographic hip OA was defined as a K/L radiographic severity grade $\geq$2 (i.e., presence of at least probable joint space narrowing [JSN] in either the superolateral or superomedial hip joint, as well as presence of an osteophyte) and severe radiographic hip OA was defined as K/L $\geq$ 3. We defined an individual as having radiographic hip OA if at least one of the hip joints was affected. In addition, symptomatic hip OA was defined as having hip pain with corresponding radiographic OA in the same hip. Prevalence of total prevalence of hip OA (%) = (total number of subjects who were diagnosed as radiographic hip OA/total subjects who participated in the X-ray examination) $\times$ 100.

Individuals who had undergone a total hip arthroplasty (THA) were defined as having severe radiographic hip OA in that joint ($n = 13$ subjects; 18 hips). However at the time of analysis of the association with hip pain, we excluded all subjects who had undergone a THA.

Statistical analysis

Odds ratios (ORs) and 95% confidence intervals (95% CIs) are provided. Differences of age and BMI between men and women were examined by non-paired *t*-test. Differences in age, height, weight, and BMI among the urban, mountainous, and coastal communities were determined using one-way analysis of covariance and Tukey's honestly significant difference test. We used the chi square test to compare the prevalence of radiographic hip OA between men and women. Association of prevalence with age was determined by logistic-regression analysis after adjustment for BMI. Association of the variables such as age, BMI, gender, and community with radiographic hip OA was evaluated by multivariate logistic-regression analysis. Logistic-regression analyses were used to estimate OR and the associated 95% CI of K/L = 2 and K/L $\geq$ 3 hip OA for pain compared with K/L = 0/1 after adjustment for age, BMI, and community. Data analyses were performed using SAS version 11.0 (SAS Institute Inc., Cary, NC).

Results

Characteristics of participants

Of the 3040 subjects in the present study, 62 (2.0%) did not undergo plain radiography, 1 (0.03%) had just experienced bilateral hip fractures, and 2 (0.07%) could not read; these subjects were excluded. The remaining 2975 subjects (95.8%) (1043 men and 1932 women), aged 23–94 years (mean 70.2 years), were included in this study (Table I). Men were significantly older than women in the overall population and in the urban population. Although the coastal residents tended to show higher body height and weight than residents in the other two communities, BMI was comparable among the three communities.

Prevalence of radiographic hip OA, hip pain, and symptomatic hip OA

Table II shows the prevalence of radiographic hip OA, severe radiographic hip OA, including unilateral and bilateral hip OA, hip pain, and symptomatic hip OA in the overall population and subgroups classified by gender and community. In the overall population, the prevalence of radiographic hip OA was 15.7%, severe radiographic hip OA was 2.12%, and that of hip pain was 1.86%. The prevalence of K/L $\geq$ 2 and K/L $\geq$ 3 symptomatic hip OA was 0.75% and 0.64%. The prevalence of radiographic hip OA was significantly higher in men than in women, but that of severe radiographic hip OA, hip pain, and symptomatic hip OA was significantly higher in women than in men. The prevalence of radiographic hip OA and hip pain were not significantly associated with age in either gender [Fig. 1]. Table II also shows the prevalence of radiographic hip OA classified by the regions. In the urban region, the prevalence of K/L $\geq$ 2 hip OA was 9.4% in men and 6.0% in women, respectively, and that of K/L $\geq$ 3 was 0.89% and 2.13%, respectively. In the mountainous region, the prevalence of K/L $\geq$ 2 hip OA was 16.4% in men and 16.1% in women, respectively, and that of K/L $\geq$ 3 was 0.63% and 2.59%, respectively. In the coastal region, the prevalence of K/L $\geq$ 2 hip OA was 34.7% in men and 25.4% in women, respectively, and that of K/L $\geq$ 3 was 2.89% and 3.11%, respectively. In the urban and mountainous regions, the prevalence of K/L $\geq$ 2 hip OA was significantly higher in men than in women, and in the coastal region, the prevalence of K/L $\geq$ 3 hip OA was significantly higher in women than in men.

Characteristics of participants classified by presence or absence of hip OA and hip pain

Mean age of subjects with and without radiographic hip OA was 70.4 ± 10.4 and 70.2 ± 11.2 years, respectively ($P = 0.68$). Mean age of subjects with and without severe radiographic hip OA was 72.5 ± 9.3 and 70.1 ± 11.1 years, respectively ($P = 0.05$), and that of subjects with and without hip pain was 67.6 ± 13.6 and 70.2 ± 11.1 years, respectively ($P = 0.16$).

Association of radiographic hip OA with hip pain

Table III shows the association of age, BMI, gender, and community with radiographic hip OA, severe radiographic hip OA, and hip pain. BMI was classified as normal (18.5 $\leq$ BMI < 25.0), thin (BMI < 18.5), obesity (25.0 $\leq$ BMI < 27.5), and high obesity (BMI $\geq$ 27.5). BMI $\geq$ 27.5, female sex, and community were significantly associated with radiographic hip OA. Female sex and coastal community were significantly associated with severe radiographic hip OA. Only female sex was significantly associated with hip pain. We then determined independent associated factors using a multiple logistic regression analysis that included the above significant

Table I
Characteristics of participants

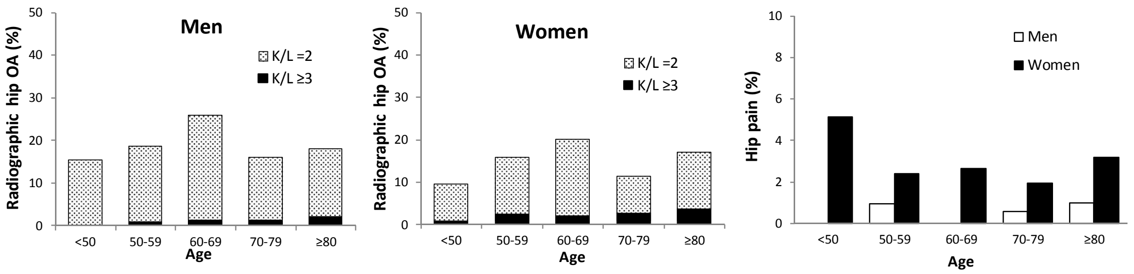
	Men				Women			
	Overall	Urban	Mountainous	Coastal	Overall	Urban	Mountainous	Coastal
Number of subjects	1043	449	317	277	1932	845	540	547
Age (years)	71.0 ± 10.7	77.2 ± 4.2	69.5 ± 9.1†	62.6 ± 13.2†	69.8 ± 11.3*	76.3 ± 5.0*	68.6 ± 10.4†	60.8 ± 12.5†
Height (cm)	162.5 ± 6.7	161.3 ± 5.9	161.3 ± 6.9	165.8 ± 6.8†	149.8 ± 6.5*	148.6 ± 5.6*	148.2 ± 6.7*	153.2 ± 6.2*,†
Weight (kg)	61.3 ± 10.0	60.1 ± 8.7	60.0 ± 10.2	64.8 ± 11.0†	51.5 ± 8.6*	50.7 ± 8.4*	50.5 ± 8.6*	53.5 ± 8.8*,†
BMI (kg/m^2)	23.2 ± 3.1	23.1 ± 2.9	23.0 ± 3.0	23.5 ± 3.4	22.9 ± 3.5*	23.0 ± 3.5	23.0 ± 3.3	22.8 ± 3.6*

Data are means ± SD.
BMI, body mass index.
* $P < 0.05$ vs men in the corresponding group by non-paired t-test.
† $P < 0.05$ vs urban residents in the corresponding group by Tukey's honestly significant difference test.

Table II
Number (percentage) of participants with radiographic hip osteoarthritis, hip pain, and their combination

	Total ($n = 2975$)	Men ($n = 1043$)				Women ($n = 1932$)			
		Overall	Urban	Mountainous	Coastal	Overall	Urban	Mountainous	Coastal
K/L $\geq$ 2 hip OA									
Total	467 (15.7)	190 (18.2)	42 (9.4)	52 (16.4)	96 (34.7)	277 (14.3)*	51 (6.0)*	87 (16.1)	139 (25.4)*
Unilateral	278 (9.3)	103 (9.9)	29 (6.5)	30 (9.5)	44 (15.9)	175 (9.1)	36 (4.3)	55 (10.2)	84 (15.4)
Bilateral	189 (6.4)	87 (8.4)	13 (2.9)	22 (7.1)	52 (19.0)	102 (5.3)*	15 (1.8)	32 (6.0)	55 (10.1)*
K/L $\geq$ 3 hip OA									
Total	63 (2.12)	14 (1.34)	4 (0.89)	2 (0.63)	8 (2.89)	49 (2.54)*	18 (2.13)	14 (2.59)*	17 (3.11)
Unilateral	37 (1.24)	7 (0.67)	2 (0.45)	1 (0.32)	4 (1.44)	30 (1.55)*	13 (1.54)	10 (1.85)	7 (1.28)
Bilateral	26 (0.88)	7 (0.68)	2 (0.45)	1 (0.32)	4 (1.46)	19 (0.99)	5 (0.60)	4 (0.75)	10 (1.84)
Hip pain	55 (1.86)	6 (0.58)	3 (0.68)	0	3 (1.08)	49 (2.56)*	23 (2.77)*	11 (2.05)*	15 (2.75)
Symptomatic hip OA									
K/L $\geq$ 2	22 (0.75)	3 (0.29)	1 (0.23)	0	2 (0.72)	19 (0.99)*	8 (0.96)	5 (0.93)	6 (1.10)
K/L $\geq$ 3	19 (0.64)	2 (0.20)	1 (0.23)	0	1 (0.36)	17 (0.89)*	6 (0.72)	5 (0.93)	6 (1.10)

* $P < 0.05$ vs men in the corresponding group by chi-squared test.



(A) (B)

Fig. 1. (A) Prevalence (percentage) of subjects with radiographic hip osteoarthritis in each age stratum (<50, 50–59, 60–69, 70–79, ≥80). (B) Prevalence (percentage) of subjects overall with hip pain in each age stratum.

factors in the univariate model. The results were similar to the crude odds ratios.

When we considered hip pain in 5891 hips, we evaluated the association between K/L grade and hip pain in the designated hip. Figure 2 shows the percentage of subjects with hip pain in subgroups classified by radiographic hip OA severity: K/L = 0/1, K/L = 2, and K/L ≥ 3. In the overall population, the percentage of K/L = 0/1 was 0.75% (0.17% in men and 1.05% in women, respectively), that of K/L = 2 was 0.71% (0.78% and 0.64%, respectively), and that of K/L ≥ 3 was 36.2% (11.1% and 45.1%, respectively). In the urban community, the percentage of K/L = 0/1 was 0.79% (0.24% in men and 1.07% in women, respectively), that of K/L = 2 was 2.17% (0% and 4.65%, respectively), and that of K/L ≥ 3 was 42.1% (25.0% and 46.7%, respectively). In the mountainous community, the percentage of K/L = 0/1 was 0.40% (0% in men and 0.63% in women, respectively), that of K/L = 2 was 0%, and that of K/L ≥ 3 was 33.3% (0% and 40.0%, respectively). In the coastal community, the percentage of K/L = 0/1 was 1.08% (0.25% in men and 1.45% in women, respectively), that of K/L = 2 was 0.66% (1.47% and 0%, respectively), and that of K/L ≥ 3 was 34.4% (9.1% and 47.6%, respectively). Although the percentage with pain was positively correlated with radiographic severity, the difference between K/L = 2 and K/L ≥ 3 appeared to be greater than that between K/L = 0/1 and K/L = 2 in the overall population and all communities. Compared with K/L = 0/1, the OR of K/L ≥ 3 hip OA for hip pain was high, whereas that of K/L = 2 was not significantly associated with hip pain, even after adjustment for age, BMI, and community (Table IV).

Discussion

This is the first large-scale, population-based study to examine the prevalence of radiographic hip OA in Japanese men and women. We found that 15.7% of subjects had radiographic hip OA, 2.12% of subjects had severe radiographic hip OA, and 0.75% of subjects had symptomatic hip OA in at least one hip. We also examined the relation between the prevalence of radiographic hip OA, sex, and age. The present study showed factors associated with hip OA and the association of hip OA with hip pain.

Few studies have examined the prevalence of radiographic hip OA in Japan[3,15]. In 2000, Inoue *et al.* estimated the prevalence of K/L ≥ 3 hip OA among Japanese aged 20–79 years to be 1.4% in men and 3.5% in women, but their subjects were patients who underwent intravenous urography, who may not be representative of a general Japanese population. To the best of our knowledge, our previous study was the only population-based study to estimate the prevalence of hip OA among Japanese subjects; results showed that the prevalence of Croft grade ≥3 hip OA was 0% in men and 2% (95% CI 0.04–4.0) in women aged 60–79 years, but this study was published in 1998[3,16]. Because of the increasing number of elderly subjects in Japan, it is likely that these data have changed since our previous study. Furthermore, in Japan, previous studies showed only the prevalence of severe radiographic hip OA, but the prevalence of radiographic hip OA (e.g., K/L ≥ 2) was not reported. In the present study, we examined the prevalence of radiographic hip OA and severe radiographic hip OA using a large-scale, population-

Table III
Association factor for radiographic hip osteoarthritis and hip pain*

	Radiographic hip OA						Hip pain	
	K/L grade ≥2			K/L grade ≥3				
	No. of subjects (%)	Crude OR (95%Cl)	Adjust OR (95%Cl)	No. of subjects (%)	Crude OR (95%Cl)	Adjust OR (95%Cl)	No. of subjects (%)	Crude OR (95%Cl)
Age (+1 years)	–	1.00 (0.99–1.01)	–	–	0.98 (0.95–1.004)	–	–	1.02 (0.996–1.04)
BMI (kg/m^2)								
18.5≤, <25.0	297 (14.9)	Reference	Reference	37 (1.86)	Reference	–	33 (1.66)	Reference
<18.5	28 (13.1)	0.86 (0.56–1.28)	0.80 (0.51–1.22)	5 (2.34)	1.26 (0.43–2.97)	–	5 (2.34)	1.42 (0.48–3.36)
25.0≤, <27.5	74 (16.3)	1.11 (0.83–1.45)	1.09 (0.81–1.45)	9 (1.98)	1.07 (0.48–2.13)	–	12 (2.64)	1.61 (0.79–3.05)
≥27.5	66 (23.0)	1.70 (1.25–2.29)	1.83 (1.32–2.51)	10 (3.48)	1.91 (0.89–3.73)	–	5 (1.75)	1.06 (0.36–2.50)
Sex								
Men	189 (18.2)	Reference	Reference	13 (1.25)	Reference	Reference	6 (0.58)	Reference
Women	276 (14.5)	0.76 (0.62–0.93)	0.76 (0.62–0.95)	48 (2.51)	2.03 (1.13–3.92)	2.11 (1.17–4.09)	49 (2.57)	4.53 (2.09–11.85)
Community								
Urban	91 (7.18)	Reference	Reference	20 (1.58)	Reference	Reference	26 (2.06)	Reference
Mountainous	139 (16.2)	2.51 (1.90–3.32)	3.45 (2.59–4.62)	16 (1.87)	1.19 (0.60–2.30)	1.62 (0.81–3.19)	11 (1.29)	0.62 (0.29–1.23)
Coastal	235 (28.6)	5.16 (3.99–6.74)	10.08 (7.48–13.68)	25 (3.04)	1.95 (1.08–3.58)	3.47 (1.78–6.74)	18 (2.19)	1.07 (0.57–1.95)

* Adjusted odds ratios (ORs) were calculated by multiple logistic regression analysis after adjustment for all other variables in addition to regions. We show all variables we analyzed in the present study. K/L = Kellgren/Lawrence; 95%CI = 95% confidence interval; BMI = body mass index.

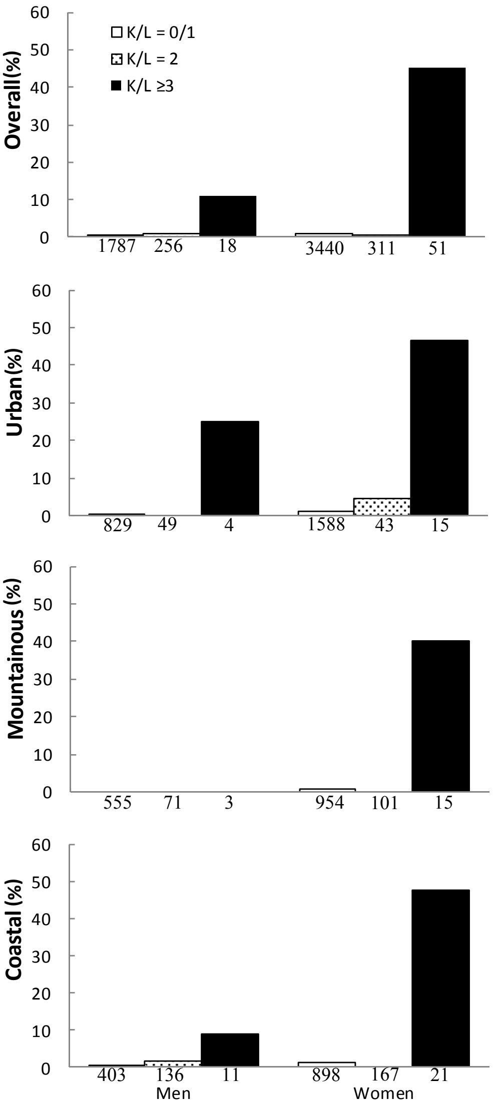


Fig. 2. Proportion (percentage) of subjects with hip pain in each subgroup classified by K/L grade in the overall population and communities. The number of subjects in each subgroup is shown under the bars. K/L, Kellgren/Lawrence.

based study and found that the prevalence of radiographic hip OA was 18.2% in men and 14.3% in women.

Although strict comparisons may be limited because the definitions of hip OA differ among studies and interobserver reliability for categorical methods is not good, the prevalence of hip OA in the present study is much lower than that seen in studies of Caucasians. In the Framingham study, the prevalence of K/L $\geq$ 2 hip OA was 24.7% (95% CI 20.6–28.7) and 13.6% (95%CI 10.7–16.5) in men and women, respectively[8]. The Johnston County prevalence study, a prevalence survey of a rural community in the United States, reported that the prevalence of K/L $\geq$ 2 hip OA was 27.6% (95%CI 26.3–28.9) and that of severe radiographic hip OA was 2.5% (95%CI 2.2–3.0)[6]; African Americans had a higher prevalence of hip OA than Caucasians. In the Rotterdam study, the prevalence of K/L $\geq$ 2 hip OA was 15.0% and that of K/L $\geq$ 3 hip OA was 4.3%[1]. In contrast, in a Beijing study, the prevalence of radiographic hip OA was 1.1% in men and 0.9% in women, which are similar or lower than values in the present study[7]. It is thought that the prevalence of hip OA is low in Asia[3,7,15,17,18], and that of severe radiographic hip OA is lower in Asians than in Caucasians; however, the presence of radiographic hip OA was not as low in the present study. These findings suggest that some ethnic factors may affect hip OA.

In the present study, coastal residency was significantly associated with radiographic hip OA, including severe radiographic hip OA, even after adjustment for age and BMI, indicating the involvement of environmental factors like nutrition or occupation. Both rural community backgrounds and farming have long been documented to be risk factors for hip OA. In England and India, rural male farmers were shown to have a higher risk of hip OA compared to rural male non-farmers[19,20]. The principle industries in the coastal residency are farming and fishing, which demand physical activity and repetitive laborious use of the hip joints, which may partly explain the higher prevalence of hip OA in the coastal region. We also found that the prevalence of radiographic hip OA was not associated with age in either gender. In the Copenhagen study, the prevalence of radiographic hip OA was age-dependent in both genders[4], whereas in the Beijing study, it slightly increased with age in men, but it did not increase with age in women[7]. These findings may also indicate a distinct etiology of hip OA among races. In addition, we also found that the prevalence of lumbar spondylosis (LS) and knee OA was significantly associated with age in the ROAD study[10,21], which may indicate that the etiology of hip OA may be different from that of LS and knee OA.

The association of gender with hip OA is controversial. Several studies in Caucasians showed that radiographic hip OA was more prevalent in men than in women[8,22], whereas in the Johnston County study and Rotterdam study, it was more prevalent in women than in men[1,6]. Previous studies in Japan showed that hip OA was significantly more prevalent in women than in men[3,15]. In the present study, interestingly, radiographic hip OA was more prevalent in men than in women, whereas, severe radiographic hip OA was more prevalent in women. In addition, the prevalence of radiographic hip OA was much higher than that of severe radiographic hip OA in the present study. This may be because a greater number of subjects in this study had osteophytosis than JSN. We have reported that osteophytosis of the lumbar spine was more

Table IV
Association of Kellgren/Lawrence grade with hip pain*

	Overall			Men			Women		
	No. of subjects (%)	Crude OR (95%CI)	Adjust OR (95%CI)	No. of subjects (%)	Crude OR (95%CI)	Adjust OR (95%CI)	No. of subjects (%)	Crude OR (95%CI)	Adjust OR (95%CI)
K/L grade									
0/1	39 (0.75)	Reference	Reference	3 (0.17)	Reference	Reference	36 (1.05)	Reference	Reference
2	4 (0.71)	0.9 (0.28–2.35)	1.36 (0.40–3.53)	2 (0.78)	4.68 (0.61–28.38)	4.50 (0.53–31.15)	2 (0.64)	0.6 (0.10–2.01)	0.79 (0.13–2.68)
≥3	25 (37.3)	80 (43.7–141.9)	123.4 (62.1–250.5)	2 (11.1)	74.3 (9.33–478.6)	57.3 (6.06–476.9)	23 (46.9)	83 (43.4–160.3)	129.1 (61.7–279.4)

We show all variables we analyzed in the present study. K/L = Kellgren/Lawrence; 95%CI = 95% confidence interval; BMI = body mass index.
* Adjusted odds ratios (ORs) were calculated by multiple logistic regression analysis after adjustment for age, BMI and communities.

prevalent in elderly Japanese men in the ROAD study[21]. In Japan, it appears that osteophytosis is more common in men than women[23,24]. However, this may indicate that the etiology of hip OA may be different from that of LS, because of the prevalence and the association were different between hip OA and LS. BMI was associated with radiographic hip OA, but not with severe radiographic hip OA in the present study. Several studies have reported that obesity has a low association with hip OA[7,18], whereas a multi-institutional study in Japan showed that obesity was a major cause for hip OA in women[25]. The discrepancy regarding the effect of obesity on hip OA may partly explain the distinct prevalence of various severities of hip OA[26].

Like the prevalence of severe radiographic hip OA, that of hip pain and symptomatic hip OA were low in both genders in the present study compared with previous studies, which showed that prevalence of hip pain was 7–40%, and that of symptomatic hip OA was 3–11%[1,5–8]. The present study also showed that the percentage of subjects with hip pain was less than 1% in subjects with $K/L = 0/1$ and 2, whereas it was more than 10% in men and more than 40% in women with $K/L \geq 3$ hip OA. Furthermore, the OR of $K/L \geq 3$ hip OA for hip pain was approximately 80 in both genders, which is much higher that of knee OA for knee pain in our previous study ($K/L \geq 3$, OR 8.55, 95% CI 5.00–14.84 vs $K/L = 0/1$)[10]. This finding suggests that the prevalence of severe radiographic hip OA, hip pain, and symptomatic hip OA is low, but the association of hip pain with hip OA is much stronger than that for the knee.

Although the prevalence of radiographic hip OA was much higher than that of severe radiographic hip OA in the present study, the prevalence of symptomatic $K/L \geq 2$ and $K/L \geq 3$ hip OA was very low, and the difference in prevalence rates was small (0.75% and 0.64%, respectively). This finding indicates that subjects with $K/L = 2$ hip OA mostly did not have hip pain. This finding suggests that JSN, rather than osteophytosis, was associated with hip pain. We think that it is important to clarify the association of hip OA and hip pain to examine the prevalence of both $K/L \geq 2$ and $K/L \geq 3$.

There are several limitations to this study. First, regarding the selection bias of all participants of the ROAD study, we have already confirmed that participants of the ROAD study are representative of the Japanese population after comparison of anthropometric measurements and frequency of smoking and alcohol drinking between the participants and the general Japanese population. Thus, the values for the general population were obtained from the report on the 2005 National Health and Nutrition Survey conducted by the Ministry of Health, Labour and Welfare, Japan. No significant differences were identified between our participants and the total Japanese population, except that the male participants aged 70–74 years in the ROAD study were significantly smaller in terms of body structure than the overall Japanese population[12]. Unfortunately, we could not avoid the difference in the selection methods used in the three areas including the urban area, and both mountainous and coastal areas, performed during surveys in the ROAD study. Therefore, although coastal residency was significantly associated with radiographic hip OA in the present study, this factor might be affected by selection bias. Second, in the present report, we described the prevalence of hip OA with no mention of acetabular dysplasia.

In conclusion, this cross-sectional study using a large-scale population from the ROAD study clarified the prevalence of radiographic hip OA in Japanese men and women. The prevalence of radiographic hip OA was significantly higher in men than in women, but that of severe radiographic hip OA was significantly higher in women than in men and was not age-dependent in either gender. In addition, hip pain was strongly associated with $K/L \geq 3$ hip OA. Further progress, along with continued longitudinal surveys of the ROAD study, will elucidate the backgrounds of hip OA and its relation with hip pain.

Author contributions

All authors have made substantial contributions to all three of the following sections:

(1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data;
(2) drafting the article or revising it critically for important intellectual content; and
(3) final approval of the version to be submitted.

Conflict of interests

There are no conflicts of interest.

Role of funding source

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ORIGINAL ARTICLE

The effect of cartilage degeneration on ultrasound speed in human articular cartilage

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Abstract

Objectives: We investigated the effect of cartilage degeneration on ultrasound speed in human articular cartilage *in vitro*.
Methods: Ultrasound speed was calculated by the time-of-flight method for 22 femoral condyle osteochondral blocks obtained from osteoarthritis patients. In parallel, histological evaluation of specimens was performed using the modified Mankin and OARSI scores.
Results: The mean ultrasound speed was 1757 ± 109 m/s. Ultrasound speed showed significant negative correlation with OARSI score, and a decreasing tendency with high Mankin scores. Good correlation was found between the optically measured and the calculated cartilage thickness.
Conclusion: Our results show that articular cartilage degeneration has relatively little influence on ultrasound speed. In addition, morphological evaluation of articular cartilage using a preset value of ultrasound speed seems to offer relatively accurate results.

Keywords

Cartilage degeneration, Cartilage thickness, Osteoarthritis, Ultrasonography, Ultrasound speed

History

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Introduction

Osteoarthritis (OA) of the knee is a condition characterized by morphological, biochemical, molecular, and biomechanical changes in both cells and the extracellular matrix, resulting in softening, fibrillation, ulceration, and eventual loss of articular cartilage [1]. In clinical practice, plain radiography is typically used to evaluate the stage of OA [2,3]. However, this method does not allow direct imaging of the cartilage, because it only evaluates the distance between the femoral and tibial bone surfaces, and the presence of osteophytes and sclerosis of the subchondral bone. Direct imaging of cartilage has been achieved using magnetic resonance imaging (MRI), which allows morphological evaluation of articular cartilage, including the determination of cartilage thickness and volume [4], and identification of cartilage degeneration [5].

In addition to MRI, ultrasonography has also been investigated for applications allowing the direct evaluation of articular cartilage, including degenerative changes in cartilage [6] and cartilage surface roughness [7]. Ultrasonography was also used in previous investigations to visualize articular cartilage and evaluate cartilage thickness, either directly on the surface of cartilage [8,9] or percutaneously [10–12]. In these studies, the set-up speed value of the diagnostic ultrasound device (1540 m/s) was used for the calculation of cartilage thickness [13]. Theoretically, however, for quantification of cartilage thickness or volume using ultrasonography, the actual ultrasound speed in each articular cartilage should be measured, since the speed of sound might differ among tissues, and thus affect the calculations [14].

Studies have been performed in articular cartilage to investigate the effect of degeneration and other factors on ultrasound speed, mostly using animal samples [15]. These studies have shown that the speed of sound in cartilage can be affected by composition [16,17], material properties [17,18], or mechanical strain [19–21], as well as by orientation of collagen fibrils [22] or anisotropy [23] of articular cartilage. Cartilage ultrasound speed can also be affected by external factors, such as the ultrasound beam angle against the cartilage surface [24], and temperature or saline concentration [23].

Some studies have investigated ultrasound speed in human articular cartilage. Based on experimental results on bovine cartilage and the results of a previous study on human cartilage, Toyras et al. [17] performed simulations investigating the relationship between the speed of sound, cartilage thickness, and the error in dynamic modulus; they suggested that a constant speed of sound can be utilized to obtain a clinically acceptable accuracy for cartilage thickness and modulus. However, relatively variable mean values for ultrasound speed have been reported in human articular cartilage (1658 m/s [25], 1892 m/s [26], ca. 1580 m/s [20]). In bovine cartilage, ultrasound speed decreases as the cartilage degenerates through chemical treatment [17]. In addition, ultrasound speed in cartilage of OA patients was reported to be lower than in normal cartilage [25]. Since it would be difficult to measure a patient-specific value of ultrasound speed in cartilage and apply this value for each patient during clinical morphological

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evaluation of cartilage, the relationship between ultrasound speed and the degree of degeneration in human cartilage warrants further investigation.

The aim of this study was to perform measurements of ultrasound speed, histologically score the degeneration in human cartilage samples, and to investigate the correlation between cartilage degeneration and ultrasound speed, in order to investigate the feasibility of using a constant value of speed in morphological evaluation of articular cartilage by ultrasound.

Methods

Cartilage sample preparation

All procedures used in this investigation were approved by the institutional review board at our university. Subjects comprised 11 OA patients who planned to undergo total knee arthroplasty and provided written informed consent prior to participation in the study. All the patients were female, with an average age of 73.2 ± 8.0 years (range: 56–83 years). Pre-operation plain radiographs showed that the Kellgren–Lawrence score [27] of all the patients was grade 4. Osteochondral blocks removed from the medial and lateral femoral condyles during operation were wrapped in gauze moistened with normal saline, packed in plastic bags, manually degassed, hermetically sealed, and stored at $-60\,^{\circ}$C. A total number of 22 osteochondral blocks from femoral condyles were acquired from the patients through operations. On the day of the experiment, the osteochondral samples were thawed in normal saline solution (Otsuka Pharmaceutical, Tokyo, Japan) at room temperature ($20\,^{\circ}$C). Osteochondral blocks from the femoral condyle were trimmed by a band saw (SWD-250; Fuijiwara Sangyo, Miki, Japan), achieving a surface size of approximately 18 mm × 18 mm for cartilage samples. Trimming was performed to obtain a sample containing sufficient quantities of cartilage for the acoustic and microscopic measurements, preferably from the part of the block closest to the weight-bearing area. Samples were then fixed on a custom-made acryl sample holder (30 mm × 30 mm × 13 mm; Murai & Co., Tokyo, Japan) with resin (GC-Ostron; GC Corporation, Tokyo, Japan) (Figure 1). During preparation, samples were continuously cooled at $20\,^{\circ}$C and moistened using normal saline solution.

Acoustic measurements

Acoustic measurements were performed using a custom-made apparatus (Figure 1). The acryl holder with the human osteochondral block affixed was positioned in a water tank containing normal saline ($20\,^{\circ}$C), so that the cartilage surface faced upward. A stage underneath, with three micrometers (accuracy, 10 μm), allowed horizontal movement of the sample. Two micrometers, perpendicular to each other in the horizontal plane, were used for position adjustment by linear movement (*x*- and *y*-axes). The third micrometer enabled circular movement in the horizontal plane (rotation movement in the *x*–*y*-plane). An ultrasound transducer was placed over the sample in the water tank, and the holder of the transducer had a *z*-adjustment device so that the distance between the cartilage surface and the transducer could be kept at the transducer focus distance (2.5″=63.5 mm).

Ultrasound measurements were performed using the A-mode pulse-echo method and a focused non-contact ultrasound transducer (V311-SU; Olympus NDT, Waltham, MA) (center frequency = 7.3 MHz, 3.4–11.2 MHz, −3 dB; transducer tip diameter = 16 mm; element diameter = 13 mm; radius of curvature = 63.5 mm). Acoustic pulses were excited electrically using a pulser/receiver board (NDT-5800; Olympus NDT). Echoes of the transmitted pulse were recorded with the transducer and pulser/receiver board. A bandpass filter (1.0–20.0 MHz) was used to enhance the ultrasound signal-to-noise ratio. The signal was digitized at a 1000-MHz sampling frequency using an oscilloscope (DPO4034; Tektronix Japan, Tokyo, Japan).

For acoustic measurements, the edges and the center point of the 30 mm × 30 mm acryl sample holder surface were first identified by moving the stage horizontally under the fixed ultrasound beam. The cartilage surface was then scanned with the ultrasound transducer by moving the stage to identify the top cartilage surface point (point C) (Figure 2). The ultrasound beam was, theoretically, perpendicular to the cartilage surface at this point, as the cartilage of the femoral condyle has a convex surface. After identifying the coordinates for this point as (a, b), two additional points at 1 mm apart on each side of this point were set as radiofrequency signal acquisition points, along with point C. The x–y coordinates of the two points were thus (a+1, b), (a−1, b) using units of 1 mm.

RF signals at these three points were acquired and output from the oscilloscope device as comma-separated values data. Time of flight was measured in each sample using the peak envelope method previously described [28] (Figure 3). The envelope of each RF signal was calculated using a Hilbert transform [29]. Peaks of the envelope signal were attributed to reflections occurring at the cartilage surface and at the cartilage-bone interface. Time of flight was defined as the duration (Δt) between peaks, corresponding to the travel time of the ultrasound pulse back and forth between the cartilage surface and the cartilage-bone interface of the specimen.

Microscopic optical thickness measurement and calculation of ultrasound speed

In order to measure cartilage thickness, direct optical measurement using microscopy was performed on a cross-section of the sample. The acryl holder with the osteochondral sample was attached to the holding arm of a diamond saw device (Minitom; Struers, Cleveland, OH) such that the saw blade was vertical to the holder top surface, that is, vertical to the *x*-*y* plane of the sample coordinates and parallel to the *y*-axis. By adjusting the position of the arm within an accuracy of 10 μm, cut planes were created, each containing 3 RF signal acquisition points. Subsequently, each cut sample was mounted on a glass slide and covered with a cover glass after dripping normal saline onto the sample surface, to keep the cartilage moist and inhibit deformation due to drying during measurement.

Cartilage thickness [4] was measured using an optical measuring microscope (×30 magnification) (MM-400; Nikon, Tokyo, Japan) containing an eyepiece with adjustable crosshairs, and an adjustable stage system (MHS 2 × 2; Nikon) (Figure 4). With the optical measuring microscope and the stage, the center point of the sample holder could be identified by measuring the distance from both edges of the sample holder, and then the RF signal acquisition points could be determined in a similar manner. The microscope could also align the sides of the sample holder, which were parallel to the direction of the ultrasound beam in RF signal acquisition, to the direction of thickness measurement. After these adjustments, cartilage thickness (d_C) along the beam direction was measured at each RF acquisition point, and the speed of sound in cartilage (SOS_C) at each point was calculated as follows:

$$\mathrm{SOS_C} = \frac{2d_\mathrm{C}}{\Delta t}. \tag{1}$$

Histological evaluation

Each osteochondral sample was fixed in 4% paraformaldehyde phosphate buffer solution (Wako Pure Chemical Industries, Osaka,

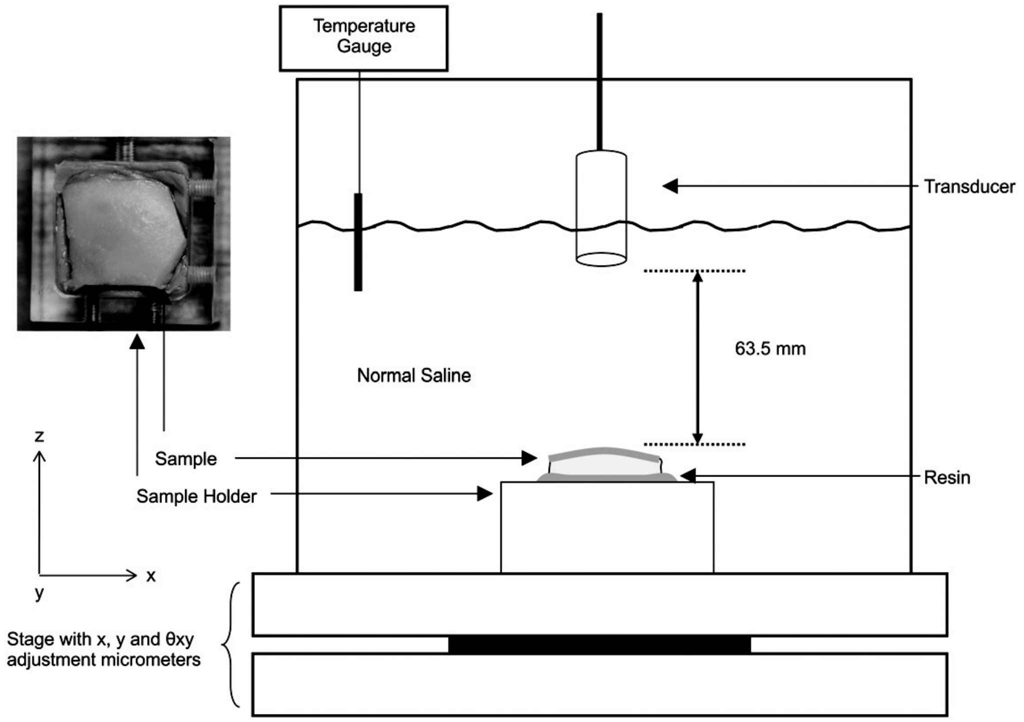

Figure 1. Custom-made apparatus for acoustic measurements. A human cartilage sample with subchondral bone was immersed in normal saline and fixed on the sample holder by resin. The water tank has a stage underneath with three micrometers (x-, y- directions and rotation movement in the x–y plane) to allow horizontal movement of the sample.

Japan) for 4 days, followed by decalcification with Plank-Rychlo's Solution composed of 0.3 M aluminum chloride, 3% hydrochloric acid, and 5% formic acid for 36 h. After decalcification, all specimens were dehydrated with ethanol, embedded in paraffin and sectioned by microtome with a thickness of 4 μm. Fast Green and Safranin O stainings were performed, and specimens were histologically evaluated using the modified Mankin score [30,31] and the Osteoarthritis Research Society International (OARSI) score [32] by two well-experienced examiners (Tables 1 and 2) (Figure 5). Histological evaluation was carried out twice by each examiner with an interval of two weeks and the mean score was used for statistical analysis.

Statistical analysis

SOS_C was defined as the mean ultrasound speed of the three acoustic measurement points in each sample. In order to assess the reliability of the histological evaluation, intraclass correlation coefficients (ICCs) comparing the first and second histological scores of each examiner were evaluated for intraobserver reliability. In addition, ICC calculation and linear regression analysis were performed to assess interobserver reliability, comparing the mean of the first and second histological scores of the specimens between the two examiners.

Spearman's rank correlation coefficient between SOS_C and the histological scores of the first examiner's first scoring as well as the correlation coefficient between SOS_C and d_C were calculated to investigate the influence of cartilage degeneration and cartilage thickness on ultrasound speed. Correlation analysis was also performed between d_C and histological scores to investigate the degree of confounding between them. In addition, to investigate the feasibility of using a preset value of ultrasound speed in thickness measurements of articular cartilage using ultrasound, linear regression analysis and Bland–Altman plot analysis were performed between optical thickness measurement values (d_C-optical) and thickness values calculated from time of flight using the average ultrasound speed of this study (d_C-US).

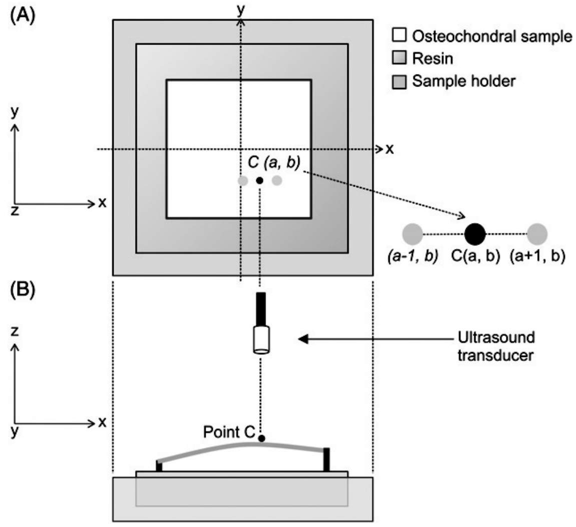

Figure 2. (A) The cartilage surface point closest to the transducer (point C) was acoustically identified. (B) With point C as the center point, radiofrequency signals were acquired at three points, each 1 mm apart. Units in the figure are 1 mm.

Statistical analysis was performed using IBM SPSS Statistics version 21.0 software (IBM, Armonk, NY), and results were considered significant for values of $p < 0.05$.

Results

In all RF signals, peaks of the reflected ultrasound wave envelopes from the cartilage surface and the cartilage-bone interface were clear enough to be identified. The mean SOS_C of all articular

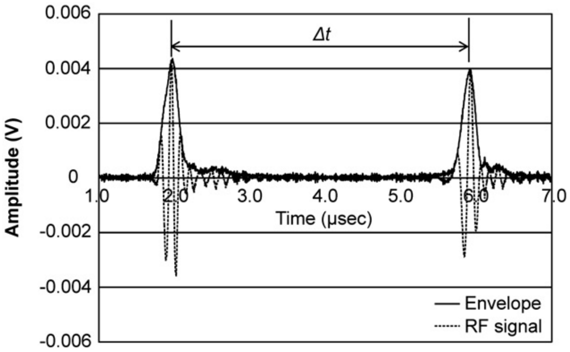

Figure 3. The graph shows an example of the radiofrequency [30] signal wave and the envelope wave calculated from the RF signal. Time of flight (Δt) was defined as the duration between peaks of the envelope wave.

cartilage samples was 1757 ± 109 m/s. The mean standard deviation calculated from the standard deviation of the three-point ultrasound speed values of individual samples was 55.2 m/s. The mean coefficient of variance calculated from each sample's SOS_C and standard deviation of the three-point ultrasound speed values was 3.2%.

ICCs for intraobserver reliability of examiner 1 and examiner 2 were 0.888 [95% confidence interval (CI), 0.753–0.952] and 0.914 (95% CI, 0.807–0.963) [overall, 0.904 (95% CI, 0.832–0.947)] for the modified Mankin score, and 0.927 (95% CI, 0.834–0.969) and 0.945 (95% CI, 0.874–0.977) [overall, 0.935 (95% CI, 0.885–0.964)] for the OARSI score, respectively. ICCs for interobserver reliability were 0.717 (95% CI, 0.438–0.871) for the modified Mankin score, and 0.965 (95% CI, 0.919–0.985) for the OARSI score. Significant linear correlation was noted between the histological scores of the two examiners by linear regression analysis ($r = 0.783$; root mean square error, 1.87; $p < 0.01$; slope, 1.24 for the modified Mankin score and $r = 0.967$; root mean square error, 0.310; $p < 0.01$; slope, 1.05 for the OARSI score).

The scatter plots for SOS_C and histological scores are shown as Figure 6. SOS_C showed a decreasing tendency with high modified Mankin scores ($r = -0.330$; $p = 0.134$), and significantly correlated with the OARSI score ($r = -0.483$; $p < 0.05$). In addition, SOS_C showed a significant positive correlation with cartilage thickness ($r = 0.484$, $p < 0.05$). There were no significant correlations between cartilage thickness and the modified Mankin score ($r = -0.253$; $p = 0.256$) or OARSI score ($r = -0.420$; $p = 0.052$).

Using the average SOS_C value, linear regression analysis showed a significant correlation between cartilage thickness measured optically and cartilage thickness calculated by time of flight (Figure 7A) ($r = 0.959$; root mean square error, 0.194 mm; $p < 0.01$; slope, 1.053). Bland–Altman plots showed a mean difference of 0.0478 mm with a standard deviation of 0.188 mm between d_C-optical and d_C-US (Figure 7B).

Discussion

Several studies have measured ultrasound speed in human articular cartilage, reporting a relatively wide range of values (1658 and 1581 m/s for normal and OA femoral cartilage, respectively [25]; 1892 m/s for the ankle joint and hip joint cartilage of one patient [26]; and ca. 1580 m/s for patellar cartilage [20]). Since cartilage degeneration has been reported to influence ultrasound speed in articular cartilage in animal studies, degeneration might be one of the reasons behind the observed differences [17,33]. We performed ultrasound speed measurements in human articular cartilage and investigated the influence of cartilage degeneration on ultrasound speed. As a result, we obtained a mean ultrasound speed of 1757 m/s, which is comparable to values reported for human articular cartilage in a previous study [26], but is higher than measurements in two other studies [20,25], including one conducted on femoral cartilage. A possible reason accounting for this discrepancy could be swelling of the cartilage during cross-sectioning. Moreover, the cartilage sample preparation steps, such as freezing, storage, thawing, and immersion in saline, could also have contributed to the discrepancy. Although we confirmed that cartilage thickness did not change after cross-sectioning, by covering the cross-section surface with a cover glass and performing the same procedures on all the samples, we cannot exclude the possibility that swelling of the cartilage during cross-sectioning, or change of propagation properties through sample preparation, might have occurred, resulting in higher ultrasound speed values.

Since we wanted to evaluate the reliability of our method on human cartilage, we performed cartilage thickness measurements by acquisition of RF signals at three points. The mean standard deviation and the mean coefficient of variance calculated for each osteochondral sample were relatively low (55.2 m/s and 3.2%, respectively) compared with the coefficient of variance of this method published for animal cartilage (3.4% for a 6-month-old pig and 6.4% for a 3-year-old pig) [28]. However, although we validated the accuracy of the cartilage thickness measurements by cross-sectioning using the custom-made devices described in a previous study involving micro-CT [28], it would be ideal to use a less invasive method, such as the needle probe method [33–35] or the custom-made ultrasound probe method [20,21], with which more ultrasound speed measurement points can be acquired and SOS_C could be more accurate.

Ultrasound speed showed a significant negative correlation with OARSI scores used for the histological evaluation, decreasing with higher degrees of cartilage degeneration. The present study is the first to report these findings in human cartilage samples. Ultrasound speed also decreased with cartilage degeneration assessed by the modified Mankin score, although the trend was not significant. The trend between the ultrasound speed and cartilage degeneration was compatible with results of previous studies on animal cartilage [17,33]. Treatment of bovine articular cartilage with trypsin for 4 h, resulting in the digestion of proteoglycan and minor cleavage of collagen, decreased ultrasound speed [33]. In bovine articular cartilage samples obtained from different locations, ultrasound speed decreased with Mankin score and water content but increased with uronic acid and hydroxyproline levels [17]. Nevertheless, a constant speed of sound was suggested to provide a clinically acceptable accuracy for cartilage thickness (error: 7.8%) in that study.

Several factors could have affected ultrasound speed in the present study. Uronic acid and hydroxyproline levels have been reported to be lower in degenerated cartilage than in normal cartilage [36]. Amide I-rich areas in the superficial layer and carbohydrate-rich areas in the whole layer have been observed to be decreased in the human OA samples [37]. These factors might have caused changes in the acoustic properties of cartilage with age, as was also observed in a study using rat articular cartilage [38].

Instead of evaluating individual components of cartilage degeneration, we performed histological scoring, in order to ensure that we investigate the overall effect of cartilage degeneration on ultrasound speed. Mankin score has been previously reported to negatively correlate with the uronic acid and hyaluronic acid content of articular cartilage [39]. In the present study, however, the OARSI score showed a better correlation with ultrasound speed than the modified Mankin score, which we believe is an interesting finding of the two different histological

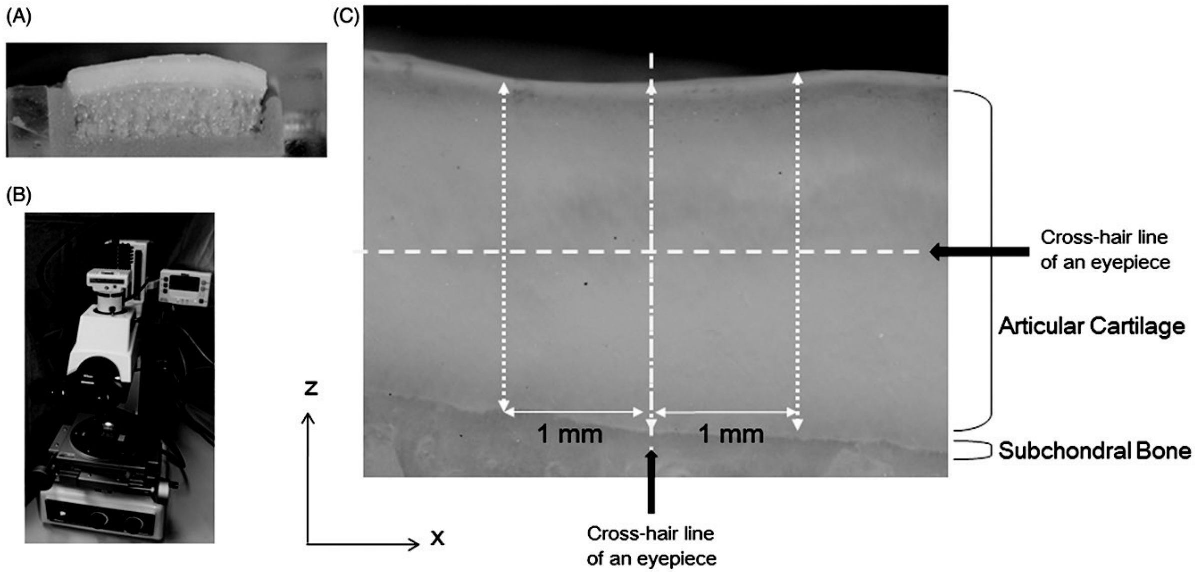

Figure 4. Images showing cartilage thickness measurement using a microscope. After registration of the RF signal acquisition points on the articular cartilage, the cut plane was created (A), containing three measurement points (B). Cartilage thickness was measured optically using a microscope (C) at the RF signal acquisition points.

Table 1. Modified Mankin score.

		Grade
I	Structure	
	Normal	0
	Surface irregularities	1
	Pannus and surface irregularities	2
	Clefts to transitional zone	3
	Clefts to radial zone	4
	Clefts to calcified zone	5
	Complete disorganization	6
II	Cells	
	Normal	0
	Diffuse hypercellularity	1
	Cloning	2
	Hypocellularity	3
III	Safranin-O staining	
	Normal	0
	Slight reduction	1
	Moderate reduction	2
	Severe reduction	3
	No dye noted	4

evaluations. A possible reason for this discrepancy could be that the OARSI score comprises not only a qualitative evaluation of articular cartilage, but also evaluation of morphological damage, a feature of advanced cartilage degeneration. In contrast, the modified Mankin score does not contain evaluation of morphological change and captures relatively early degenerative changes of articular cartilage. Indeed, we found that ultrasound speed showed a significant positive correlation with cartilage thickness, and that cartilage thickness did not correlate with the histological scores. We assume that not only cartilage degeneration, but also cartilage wear, which generally occurs in advanced OA, could have influenced the ultrasound speed. However, articular cartilage thickness can differ even between healthy individuals [40]. Thus, we assumed that cartilage wear or decrease in cartilage thickness could not be quantified in the patients in the present study because the original cartilage thickness (i.e. before OA had started) is unknown in each patient, and the positive correlation between the ultrasound speed and cartilage thickness in this study did not prove the correlation between ultrasound speed and cartilage wear.

In the present study, we found that both the modified Mankin score and the OARSI score were precise and reliable, as judged by intraobserver and interobserver reliability values, corroborating the findings of previous studies [31,41–43]. The correlation coefficient between the two scoring systems was 0.942 ($p < 0.001$), but ICCs for both intraobserver reliability and interobserver reliability were lower for the modified Mankin score than for the OARSI score. The OARSI score covers a relatively wide range of cartilage change, from early to advanced degeneration, while the modified Mankin score evaluates relatively early degenerative changes of articular cartilage. Thus, samples showing advanced degeneration might have resulted in a lower reliability for the modified Mankin score.

In a study using animal cartilage samples [17], a constant speed of sound was shown to provide a clinically acceptable accuracy for cartilage thickness. In addition, a good correlation ($r = 0.78$) was observed between the cartilage thickness calculated acoustically and the thickness measured optically in a study using human osteochondral samples [25]. Our results show an even better correlation ($r = 0.959$) between these values, although this might be due to differences in patient populations. Ultrasound intensity of the cartilage surface has been reported to significantly decrease as degeneration or OA develops, both in animals and in humans, and is suggested to have the potential to detect early osteoarthritic changes at the preclinical stage [37]. In the present study, ultrasound speed had a significant correlation with the OARSI score but not with the modified Mankin score. In addition, since it is technically difficult to measure the ultrasound speed in cartilage and apply this value for each patient during clinical morphological evaluation of cartilage, using a specific preset value of ultrasound speed seems justifiable based on our findings.

An MRI study on OA patients with OARSI grade 1, 2, and 3 medial joint space narrowing (JSN) has shown a reduced cartilage thickness (with differences of 0.190, 0.630, and 1.560 mm in the respective groups) in weight-bearing medial femorotibial compartments compared to cartilage in knees without JSN [44]. In addition, the mean annual loss of cartilage thickness in the center of the medial femoral condyle was over 0.180 mm in the grade 2 and 3 patient groups [45]. Clinical morphological evaluation of

Table 2. OARSI score.

Grade (key feature)	Subgrade
Grade 0: surface intact, cartilage morphology intact	No subgrade
Grade 1: surface intact	1.0 Cells Intact
	1.5 Cell death
Grade 2: surface discontinuity	2.0 Fibrillation through superficial zone
	2.5 Surface abrasion
	with matrix loss within superficial zone
Grade 3: vertical fissures (clefts)	3.0 Simple fissures
	3.5 Branched/complex fissures
Grade 4: erosion	4.0 Superficial zone delamination
	4.5 Mid zone excavation
Grade 5: denudation	5.0 Bone surface intact
	5.5 Reparative tissue surface present
Grade 6: deformation	6.0 Joint margin osteophytes
	6.5 Joint margin and central osteophytes

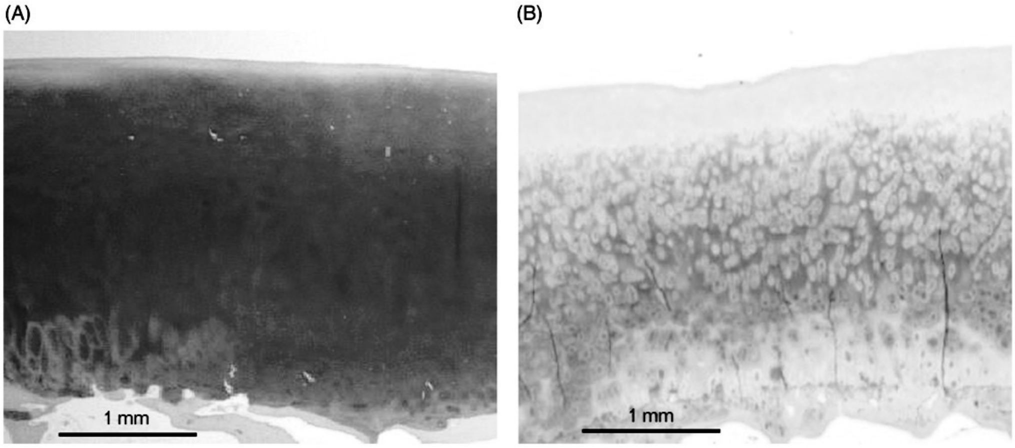

Figure 5. Representative images of histological sections stained with Fast Green and Safranin O. (A) Relatively healthy cartilage exhibits slight reduction in Safranin O staining. Histological scores were graded as 2 based on the modified Mankin score and 1 based on the OARSI score. (B) Moderately degenerated cartilage exhibits pannus/surface irregularities, diffuse hypercellularity, and moderate reduction in Safranin O staining. Histological scores were graded as 5 based on the modified Mankin score and 2.5 based on the OARSI score.

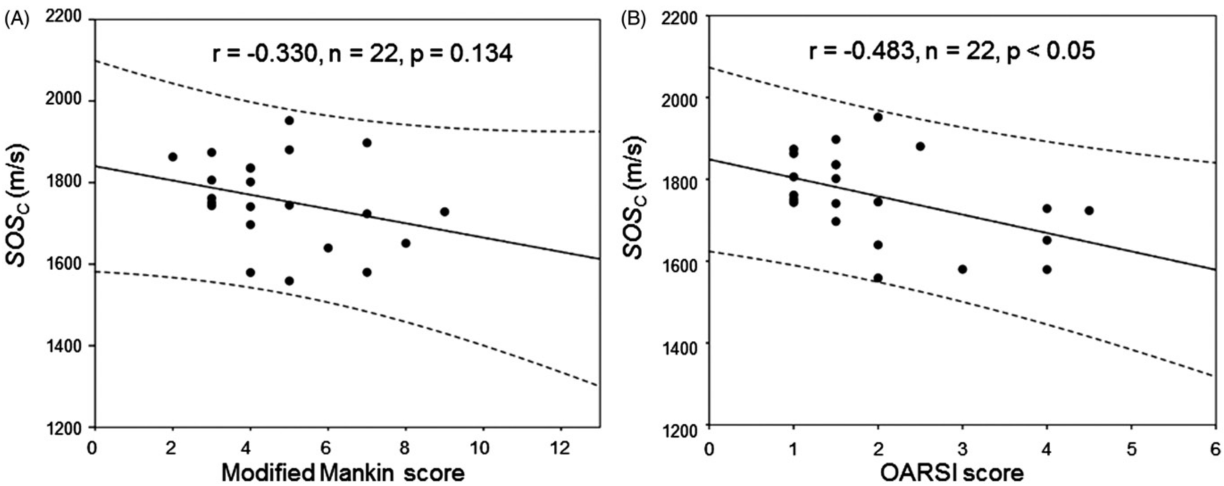

Figure 6. Scatter plots of ultrasound speed (SOS_C) and histological scores. (A) Modified Mankin score; (B) OARSI score. Spearman's rank correlation coefficients (*r*) are shown. The regression line and the 95% CIs for the population (dashes) are also shown.

articular cartilage using ultrasound is performed either percutaneously [46,47] or arthroscopically [48,49]. The ultrasound frequency used in our study is relatively close to the ultrasound frequency used clinically (5–15 MHz), and we believe that our results could be applied to both percutaneous and arthroscopic evaluation of cartilage thickness. The mean and standard deviation (0.0478 ± 0.188 mm) of the differences between ultrasonic and optical thickness in the present study assures that cartilage

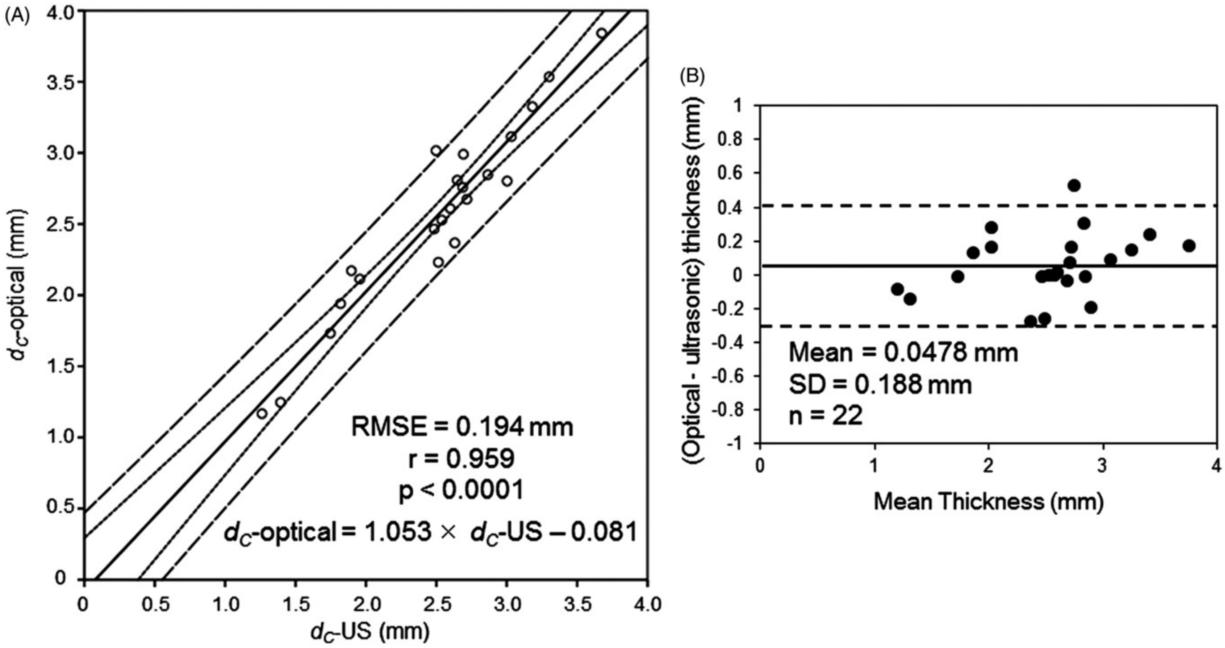

Figure 7. (A) Correlations between optical thickness measurement values (d_C-optical) and thickness values calculated using the average ultrasound speed (d_C-US). The 95% CIs for regression (short dashes) and the population (long dashes) are shown. Root mean square errors (RMSE) and Pearson's correlation coefficients (r) are also shown. (B) Bland–Altman plot analysis of the difference in d_C-optical and d_C-US compared with the mean thickness of d_C-optical and d_C-US. The line corresponding to the mean difference of d_C-optical and d_C-US and lines for mean $\pm$ 1.96 $\times$ SD (dashes) are shown.

evaluation using a specific ultrasound speed can detect clinically important differences or changes in articular cartilage thickness, considering the results of the past MRI studies.

We are aware of several limitations of our study that will require further exploration. First, we were able to collect specimens only from OA patients who underwent total joint arthroplasty. Although we performed measurements on samples with various degrees of degeneration, from relatively normal areas to degenerated lesions on the femoral condyles, probably none of the samples could be considered fully normal cartilage in this study. Ideally, normal cartilage samples are acquired from cadavers without OA of the knee. Second, we performed evaluation only on samples acquired from the knees, but not from other joints. In animal studies, ultrasound speed could differ among samples obtained from different sites [17,50]. Thus, our results cannot be automatically extrapolated to ultrasonic evaluation of cartilage of other joints, although we assume that the effect of degeneration on ultrasound speed will be similar. Finally, we did not perform a biochemical evaluation of cartilage degeneration. As mentioned before, our aim was to investigate the overall effect of cartilage degeneration on ultrasound speed. Nevertheless, performing biochemical evaluations could reveal which component of the cartilage affects ultrasound speed.

The present study has several strengths. To our knowledge, this is the first study investigating the effect of the degree of cartilage degeneration on ultrasound speed using human samples. We believe that a relatively broad range of samples, representing different degrees of degeneration, was covered in our study and that the findings of the present study support the usage of a preset ultrasound speed value in clinical morphological evaluations of cartilage. In conclusion, our results show that cartilage degeneration has relatively little influence on ultrasound speed in articular cartilage. In addition, morphological evaluation of articular cartilage using a preset value of ultrasound speed seems to offer relatively accurate values of cartilage thickness.

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Conflict of interest

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RESEARCH ARTICLE

Metabolic Syndrome Components Are Associated with Intervertebral Disc Degeneration: The Wakayama Spine Study

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Data Availability Statement: The present study used resident data from two communities in Wakayama prefecture. It is impossible for us to provide and upload these data in a public repository because we have confirmed with these municipalities and residents that data will remain confidential. We will provide anonymized data on request after discussing the contents with the municipalities, as long as researchers are qualified to request these data. Data requests can be made to the corresponding author at hashizum@wakayama-med.ac.jp.

Abstract

Objective

The objective of the present study was to examine the associations between metabolic syndrome (MS) components, such as overweight (OW), hypertension (HT), dyslipidemia (DL), and impaired glucose tolerance (IGT), and intervertebral disc degeneration (DD).

Design

The present study included 928 participants (308 men, 620 women) of the 1,011 participants in the Wakayama Spine Study. DD on magnetic resonance imaging was classified according to the Pfirrmann system. OW, HT, DL, and IGT were assessed using the criteria of the Examination Committee of Criteria for MS in Japan.

Results

Multivariable logistic regression analysis revealed that OW was significantly associated with cervical, thoracic, and lumbar DD (cervical: odds ratio [OR], 1.28; 95% confidence interval [CI], 0.92–1.78; thoracic: OR, 1.75; 95% CI, 1.24–2.51; lumbar: OR, 1.87; 95% CI, 1.06–3.48). HT and IGT were significantly associated with thoracic DD (HT: OR, 1.54; 95% CI, 1.09–2.18; IGT: OR, 1.65; 95% CI, 1.12–2.48). Furthermore, subjects with 1 or more MS components had a higher OR for thoracic DD compared with those without MS components

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Abbreviations: DD, disc degeneration; MS, metabolic syndrome; OW, overweight; HT, hypertension; DL, dyslipidemia; IGT, impaired glucose tolerance; ROAD, Research on Osteoarthritis/Osteoporosis Against Disability.

(vs. no component; 1 component: OR, 1.58; 95% CI, 1.03–2.42; 2 components: OR, 2.60; 95% CI, 1.62–4.20; ≥3 components: OR, 2.62; 95% CI, 1.42–5.00).

Conclusion

MS components were significantly associated with thoracic DD. Furthermore, accumulation of MS components significantly increased the OR for thoracic DD. These findings support the need for further studies of the effects of metabolic abnormality on DD.

Introduction

Intervertebral disc degeneration (DD) is generally considered as the first step of spinal change and undergoes destructive changes with age. It is typically followed by the loss of water and proteoglycan content of the nucleus, annulus tears, gradual formation of osteophytes, disc narrowing, and spinal canal stenosis [1, 2], and low back pain [3–6], is a major public health problem that negatively influences activities of daily living and quality of life in those affected. The number of patients with degenerative disease of the spine is increasing [6], thereby causing medical expenses to rise. In spite of these situation, the cause of DD is not fully understood. Because the etiology of DD exclude aging remains poorly understood. Accordingly, we need to clarify which risk factors promote DD to establish preventive measures against DD. In the present study, we focused on metabolic syndrome (MS) component, such as overweight (OW), hypertension (HT), dyslipidemia (DL), and impaired glucose tolerance (IGT), because MS component has some influence on atherosclerosis [7] and accumulation of MS component increase the risk of atherosclerosis events [8]. MS may increase not only the risk of cardiovascular events but also the risk of DD in the whole body [9], because intervertebral discs, which are structures with precarious nutrient supply at tissue level throughout the whole body, may suffer and gradually degenerate as a consequence of failure of nutrient supply to disc cells [10, 11]. However the association between MS component and DD remains controversial [9]. In some previous epidemiologic studies, OW [6, 12–16], DL [16], and IGT [17] were found to be associated with DD in the lumbar region. Other studies, however, have found no clear associations between hypertension (HT) [9], IGT [9, 16], and DL [9, 18], and DD in the lumbar region. This may be due to the limitation of potential biases related to patient selection and the consequences of disease on behavior. Furthermore, the majority of epidemiologic investigations have focused only on the lumbar spine. We believe that analysis of DD in the entire spine would provide more useful data than that of DD in only the lumbar region. Since the cervical and lumbar regions comprise mobile segments, the intervertebral discs in these regions are easily affected by mechanical and motion stress; thus, the effects of certain factors imposed on all intervertebral discs equally, such as age and endogenic factors, might be masked. In contrast, the thoracic region is stabilized by the thoracic cage, which reduces mechanical stress imposed on the intervertebral discs. We conducted a thorough literature review and found no studies of associations between component of MS and DD that focused on a population-based analysis using whole-spine magnetic resonance imaging (MRI).

The purpose of the present study was to examine the association of each MS component, such as OW, HT, DL, and IGT, with DD in the cervical, thoracic, and lumbar regions of the entire spine in a large population. We also examined the relationship between accumulation of MS components and DD.

Methods

Participants

The present study design was approved by the Wakayama medical university ethics committee. All participants provided their written informed consent. The present study, entitled the Wakayama Spine Study, was a population-based study of DD performed using a subcohort of the large-scale population-based cohort study called Research on Osteoarthritis/Osteoporosis Against Disability (ROAD). The ROAD study is a nationwide, prospective study of bone and joint diseases consisting of population-based cohorts established in several communities in Japan [19, 20]. A second visit of the ROAD study to the mountainous region of H town and the seacoast region of T town was performed between 2008 and 2010. From inhabitants participating in the second visit of the ROAD study, 1,063 volunteers were recruited for MRI examinations. Among the 1,063 volunteers, 52 declined to attend the examination; therefore, 1,011 inhabitants were recruited for registration in the Wakayama Spine Study. Among the 1,011 participants, those who had an MRI-sensitive implanted device (e.g., pacemaker) or other disqualifiers were excluded. Consequently, 980 individuals underwent whole-spine MRI. One participant who had undergone a previous cervical operation and 4 participants who had undergone previous posterior lumbar fusion were excluded from the analysis. Whole-spine MRI results were available for 975 participants (324 men, 651 women) with an age range of 21 to 97 years (mean, 67.2 years for men, 66.0 years for women). Thirty participants with incomplete anthropometric measurements and 17 participants without blood measurements were excluded. Finally, the present study comprised 928 participants (308 men, 620 women) with a mean age of 67.4 years.

The participants completed an interviewer-administered questionnaire of 400 items that included lifestyle information, such as smoking habit, alcohol consumption, family history, past history, occupation, physical activity, and health-related quality of life. Anthropometric measurements included height, weight, and body mass index (BMI) (weight [kg]/height [m]^2). An experienced public health nurse measured systolic and diastolic blood pressure (BP) using a mercury sphygmomanometer.

MRI

A mobile MRI unit (Excelart 1.5 T; Toshiba, Tokyo, Japan) was used in the present study, and whole-spine MRI was performed for all participants on the same day as the questionnaire and anthropometric examination. The participants were supine during MRI, and those with rounded backs used triangular pillows under their head and knees. The imaging protocol included sagittal T2-weighted fast-spin echo (FSE) (repetition time [TR], 4000 ms/echo; echo time [TE], 120 ms; field of view [FOV], 300 × 320 mm) and axial T2-weighted FSE (TR, 4000 ms/echo; TE, 120 ms; FOV, 180 × 180 mm).

Sagittal T2-weighted images were used to assess the intervertebral space from C2/3 to L5/S1. C2/3 to C7/T1, T1/2 to T12/L1, and L1/2 to L5/S1 were defined as the cervical, thoracic, and lumbar region, respectively. Grading of DD was performed by a board certified orthopedic surgeon (M.T.) who was blinded to the background of the subjects. The degree of DD on MRI was classified into 5 grades based on the Pfirrmann system [21], with grades 4 and 5 indicating DD. The signal intensity for grade 4 is intermediate to hypointense to cerebrospinal fluid (dark gray), while the structure is inhomogeneous. The signal intensity for grade 5 is hypointense to cerebrospinal fluid (black), and the structure is likewise inhomogeneous. In addition, the disc space is collapsed. It has been reported that loss of signal intensity is significantly associated with morphologic level of DD and also with water and proteoglycan content in a disc [22]. Therefore, we used a grading system based on signal intensity and disc height.

For evaluating intraobserver variability, 100 randomly selected whole-spine magnetic resonance images were rescored by the same observer (M.T.) more than 1 month after the first reading. Furthermore, to evaluate interobserver variability, 100 other magnetic resonance images were scored by 2 board certified orthopedic surgeons (M.T. and R.K.) using the same classification system. The intra- and interobserver variability for DD, as evaluated by kappa analysis, were 0.94 and 0.94, respectively.

Blood examination

All blood and urine samples were extracted between 9:00 AM and 3:00 PM. Some samples were extracted under fasting conditions. After centrifugation of the blood samples, sera were immediately placed in dry ice, and transferred to a deep freezer within 24 hours. These samples were stored at –80°C until assayed. For the samples of participants in the baseline study, the following items were measured: blood counts, hemoglobin, hemoglobin A1c (HbA1c), blood sugar, total protein, aspartate aminotransferase, alanine aminotransferase, γ-glutamyl transpeptidase, high-density lipoprotein cholesterol (HDL-C), total cholesterol, triglycerides (TGs), blood urea nitrogen, uric acid, and creatinine. These analyses were performed at the same laboratory within 24 hours after extraction (Osaka Kessei Research Laboratories Inc., Osaka, Japan).

Definitions of MS components were based mainly on the criteria of the Examination Committee of Criteria for MS in Japan [23]. According to the consensus, an abdominal circumference $\geq$85 cm in men and $\geq$90 cm in women is a necessary condition for MS. HT was diagnosed as systolic BP $\geq$130 mm Hg and/or diastolic BP $\geq$85 mm Hg; DL, as serum TG level $\geq$150 mg/dL and/or serum HDL-C level <40 mg/dL; and IGT, as fasting serum glucose level $\geq$100 mg/dL. Recently, the National Cholesterol Education Program's Adult Treatment Panel III report proposed a new set of criteria to define MS without central obesity, as indicated by waist circumference, as the core feature [24]. Furthermore, compared with BMI, measurement of waist circumference is less reproducible due to lack of uniformity in measurement methods [25, 26]. By contrast, measurement of BMI is more user-friendly and widely practiced. In this study, we decided to use BMI $\geq$25 kg/m^2 as an indicator of OW, based on the criteria of the Japan Society for the Study of Obesity [25].

In addition, because not all blood samples were obtained under fasting conditions, we did not use participants' data concerning serum levels of glucose and TGs because of their large variation depending on hours after eating. Instead, we used serum HDL-C level <40 mg/dL to indicate DL, and serum HbA1c level $\geq$5.5% to indicate IGT (the value for HbA1c (National Glycohemoglobin Standardization Program (NGSP)) (%) is estimated as an NGSP-equivalent value calculated by the formula HbA1c (%) = HbA1c (Japan Diabetes Society (JDS)) (%) + 0.4%) [27]. These are indices used in the National Health and Nutrition Survey in Japan, which were adopted as criteria for MS in this national screening based on the difficulty of collecting samples under fasting conditions [28].

Statistical analysis

All statistical analyses were performed using JMP version 8 (SAS Institute Japan, Tokyo, Japan). Differences between the groups depending on the presence or absence of DD were tested using a variance analysis. Multivariable logistic regression analysis was performed to determine the association of OW, HT, DL, and IGT with DD. The DD in the cervical, thoracic, or lumbar region was separately served as an objective variable. Then, to clarify the association

Table 1. Background characteristics of the participants.

	Overall	Men	Women
No. of participants	**928**	**308**	**620**
Mean (SD) selected characteristics			
Age (years)	67.4 (12.3)	68.5 (12.4)	66.8 (12.2)
Height (cm)	155.8 (9.4)	160.5 (8.0)	153.4 (9.1)
Weight (kg)	56.7 (11.5)	60.2 (11.4)	55.0 (11.2)
Body mass index (kg/m^2)	23.3 (3.6)	23.7 (3.3)	23.1 (3.7)
Systolic BP, mmHg	139.5 (19.6)	141.3 (18.5)	138.7 (20.0)
Diastolic BP, mmHg	76.0 (11.5)	78.1 (12.5)	74.9 (10.9)
Serum levels of HDL-C, mg/dl	63.2 (16.2)	56.0 (14.8)	66.8 (15.7)
Serum levels of HbA1c, %	5.3 (0.7)	5.3 (0.9)	5.2 (0.6)
Prevalence of selected characteristics, %			
Smoking habit	10.1	23.3	3.5
Alcohol consumption	31.2	57.5	18.2
Prevalence of each metabolic abnormality, %			
Obesity	29.4	32.5	27.9
Hypertension	74.7	78.9	72.6
Dyslipidemia	4.5	10.1	1.8
Impaired glucose tolerance	23.3	27.3	21.3

Values are the means ± standard deviation. HDL-C = high density lipoprotein cholesterol, HbA1c = glycosylated haemoglobin, ABI = ankle brachial index, SD = standard deviation

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between accumulation of MS components and DD, logistic regression analysis was repeated using presence of DD in the cervical, thoracic, and lumbar region, respectively, as the objective variable and number of MS components present as the explanatory variable, after adjusting for age, sex, regional difference, smoking habit, and alcohol consumption. P value of <0.05 was treated as significant.

Results

Table 1 shows selected characteristics of the participants, including age, height, weight, BMI, systolic and diastolic BP, and serum levels of HDL-C and HbA1c, classified by sex. Table 1 also shows the proportion of subjects who smoked (regularly or more than once a month) and consumed alcohol (regularly or more than once a month), and the prevalence of OW, HT, DL, and IGT. In the total population, the MS component with the highest prevalence was HT, followed by OW, IGT, and DL.

Table 2 shows the mean value of each MS component according to absence and presence of DD in the cervical, thoracic, and lumbar region, respectively. Mean values of age, BMI, systolic BP, and HbA1c were significantly higher, while those of HDL-C were significantly lower, in subjects with DD than in those without DD.

To determine the associations of DD with OW, HT, DL, and IGT, multivariable logistic regression analysis was performed (Table 3). OW was significantly associated with presence of DD in the cervical, thoracic, and lumbar regions. In addition, HT, DL, and IGT were significantly associated with presence of DD in the thoracic region, but not with DD in the cervical and lumbar regions.

Next, to determine the effect of accumulation of MS components on DD in the thoracic region, we examined the association of number of MS components present with DD after

Table 2. Mean value (SD) of each demographic characteristics and measurements in the absence and presence of disc degeneration in the cervical, thoracic, and lumbar region, respectively.

	Cervical			Thoracic			Lumbar		
	Presence of DD	Absence of DD	p-value	Presence of DD	Absence of DD	p-value	Presence of DD	Absence of DD	p-value
No. of participants	592	336		578	350		839	89	
Demographic characteristics and measurements									
Age (years)	70.8 (11.3)	61.4 (11.7)	0.0001	71.7 (10.3)	60.1 (11.9)	0.0001	67.7 (11.8)	64.0 (16.0)	0.007
Body mass index (kg/m^2)	23.5 (3.6)	23.0 (3.6)	0.0552	23.6 (3.7)	22.9 (3.3)	0.0058	23.4 (3.6)	22.2 (3.3)	0.0028
Systolic BP, mmHg	141.3 (19.1)	136.6 (19.9)	0.0004	142.5 (18.8)	134.7 (19.8)	0.0001	140.0 (19.8)	134.9 (16.9)	0.0188
Diastolic BP, mmHg	75.5 (11.2)	76.9 (12.1)	0.0663	75.6 (11.2)	76.7 (12.0)	0.1707	76.1 (11.5)	74.9 (12.1)	0.3362
Serum levels of HDL-C, mg/dl	61.8 (15.2)	65.7 (17.5)	0.0004	61.9 (15.4)	65.3 (17.3)	0.0022	63.2 (16.1)	63.5 (17.3)	0.853
Serum levels of HbA1c, %	5.3 (0.7)	5.2 (0.7)	0.0011	5.4 (0.8)	5.1 (0.5)	0.0001	5.3 (0.7)	5.1 (0.5)	0.0067

DD = disc degeneration, BMI = body mass index, BP = blood pressure, HDL-C = high density lipoprotein in cholesterol, HbA1c = hemoglobin A1c, SD = standard deviation

Differences between the groups depending on the presence or absence of DD were tested using a variance analysis.

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adjusting for age, sex, regional difference, smoking habit, and alcohol consumption. Fig 1. shows the odds ratio (OR) of number of MS components for presence of DD in the thoracic region. Subjects with 1 or more MS components had a higher OR for presence of DD compared with those without MS components (vs. no component; 1 component: OR, 1.58; 95% confidence interval [CI], 1.03–2.42; p = 0.0353; 2 components: OR, 2.60; 95% CI, 1.61–4.20; $p < 0.0001$; $\geq$3 components: OR, 2.62; 95% CI, 1.42–5.00; p = 0.0021).

Table 3. Association of OW, HT, DL and IGT in cervical, thoracic and lumbar region, respectively.

		Cervical		Thoracic		Lumbar	
		OR (95%CI)	p-value	OR (95%CI)	p-value	OR (95%CI)	p-value
Overweight	**Yes vs no**	1.28 (0.92–1.78)	0.1397	1.75 (1.24–2.51) *	0.0016	1.87 (1.06–3.48) *	0.0306
Hypertension	**Yes vs no**	1.19 (0.85–1.66)	0.286	1.54 (1.09–2.18) *	0.0138	0.88 (0.52–1.45)	0.6189
Dyslipidemia	**Yes vs no**	1.06 (0.49–2.17)	0.8853	0.42 (0.21–0.86) *	0.0176	0.87 (0.34–2.70)	0.7963
Impaired Glucose Tolerance	**Yes vs no**	1.27 (0.88–1.85)	0.1943	1.65 (1.12–2.48) *	0.0115	1.48 (0.80–2.95)	0.2211
Age	**over 65 vs under 65**	2.98 (2.16–4.11) * * *	<0.0001	5.76 (4.10–8.16) * * *	<0.0001	4.72 (2.47–9.69) * * *	<0.0001
Sex	**Women vs men**	1.32 (0.92–1.90)	0.1342	1.02 (0.70–1.48)	0.9198	0.95 (0.56–1.66)	0.8691
Regional difference	**Mountainous town vs seacoast town**	1.75 (1.13–2.78) *	0.012	1.20 (0.77–1.89)	0.4353	0.14 (0.07–0.27) * * *	<0.0001
Smoking habit	**Yes vs no**	0.88 (0.54–1.44)	0.6002	0.90 (0.54–1.49)	0.6707	0.56 (0.29–1.12)	0.0984
Alcohol consumption	**Yes vs no**	0.94 (0.67–1.33)	0.7332	0.96 (0.67–1.37)	0.8332	0.92 (0.55–1.55)	0.7456

Multivariable logistic regression analysis was performed to determine the association of OW, HT, DL, and IGT with DD. The DD in the cervical, thoracic, or lumbar region was separately served as an objective variable. DD = disc degeneration, OW = Overweight, HT = Hypertension, DL = Dyslipidemia, IGT = Impaired Glucose Tolerance. Overweight was diagnosed as BMI $\geq$ 25, Hypertension was diagnosed as systolic BP $\geq$ 130 mm Hg and/or diastolic BP $\geq$ 85 mm Hg, DL was diagnosed as serum HDL-C level < 40 mg/dl, Impaired Glucose Intolerance was diagnosed as serum HbA1c level $\geq$ 5.5%

OR = odds ratio, 95% CI = 95% confidence interval

*p value < 0.001

***p value < 0.0001

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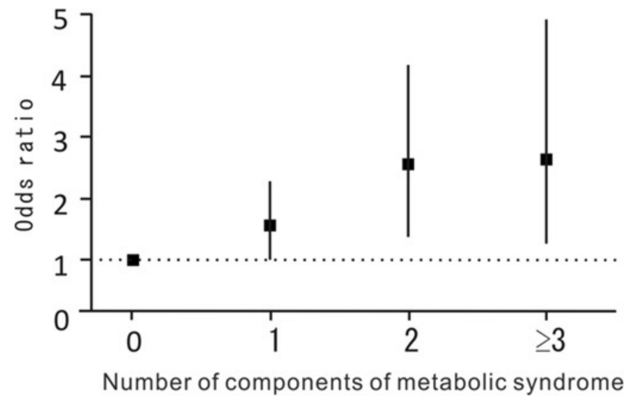

Fig 1. ORs of the number of MS components for the presence of DD in the thoracic region, compared with no components present. Subjects with 1 or more MS components had a higher OR for presence of DD compared with those without MS components.

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Discussion

The present study was the first to determine the associations between MS components and DD in the entire spine using whole-spine MRI in a large population. We elucidated that OW was significantly associated with presence of DD in the entire spine, including the cervical, thoracic, and lumbar regions. HT, DL, and IGT were significantly associated with presence of DD in the thoracic region, but not with DD in the cervical and lumbar regions. Furthermore, we also found that accumulation of MS components was significantly associated with presence of DD in the thoracic region.

Regarding the association between degenerative musculoskeletal disease and metabolic risk factors, Yoshimura et al. clarified the association between accumulation of metabolic risk factors and presence and occurrence of knee osteoarthritis (OA) [29, 30]. Hart et al. found that metabolic risk factors, such as high blood glucose level, hypercholesterolemia, and even treated HT, were associated with development of knee OA [31]. Furthermore, Anekstein et al. clarified the association between diabetes mellitus and lumbar spinal stenosis in the patients [32]. However, to our knowledge, there has been no report concerning the association between MS components and DD in the spine, especially the entire spine, using whole-spine MRI in a large population.

In the present study, OW was significantly associated with presence of DD in the cervical, thoracic, and lumbar regions. The association between OW and DD has been previously reported, and Liuke et al. found that past OW was more strongly associated with DD than present OW [13]. Samartzis et al. reported that DD in the lumbar region was significantly associated with OW and obesity [14]. On the other hand, according to Okada et al. and Matsumoto et al., DD in the cervical and thoracic regions did not have significant correlation with BMI [32, 33]. Therefore, the association remains controversial. The present study is the first to determine the association of OW with DD in the entire spine using a population-based design, and found that OW was significantly associated with DD in not only the lumbar region but also the cervical and thoracic regions. DD is influenced by inflammatory cytokines, such as adipokines, known as key metabolism mediators [34–37]. Inflammatory cytokines, such as leptin, adiponectin, and resistin, have more addressed in body fat [34, 38]. Thus, OW may lead to an increase in adipokine secretion of proinflammatory cytokines and metabolic mediators; thus, all intervertebral discs in the entire spine may be influenced by inflammatory cytokines.

Further research is needed to elucidate the mechanism through which OW affects DD since both direct mechanical stress and indirect factors affect the intervertebral discs.

To our knowledge, there has been less report regarding the association of HT with DD or lumbar spinal stenosis as spinal disorder [9, 39]. HT is a well-known risk factor for development of atherosclerosis [40]. Thus, HT might lead to vascular insufficiency to the disc, due to atherosclerosis, which can affect nutrient and metabolite transport into the disc.

The present study also confirmed the significant association between IGT and DD. In one study, it was reported that diabetic sand rats had more dehydrated discs compared with a control group [17]. In the Nurses' Health Study, IGT increased the risk of lumbar disc herniation [41]. However, several previous reports on DD also showed a weak association with IGT [9, 16, 42]; this may be due to their investigation of DD in only the lumbar region. In this study, we found an association between IGT and presence of DD in the thoracic region. Therefore, IGT, which is well known for causing microangiopathy throughout the whole body, also might be a predisposing factor for development of DD. Furthermore, advanced glycation end products accumulate in the intervertebral discs with aging, particularly when the concentration of serum glucose is high, such as in IGT [43]. Therefore, IGT might be associated with DD.

In this study, we found a negative association between DL and DD. The association of DL and DD also remains controversial in previous reports [9, 18, 44]. We believe that DD might be the result of decreased blood supply, caused by DL, to the already poorly vascularized discs [45, 46]. The mean HDL-C was higher in women than in men, as shown in Table 2. Because women in Japan use health services more frequently compared with men [28], the proportion of patients with DL in women was higher than that in men. This might have influenced the negative association between DD and DL. In a follow-up study, we will further investigate the association between DL and DD.

We found no associations of HT, DL, and IGT with DD in the cervical and lumbar regions. Since the cervical and lumbar regions comprise mobile segments, the intervertebral discs are easily affected by mechanical and motion stress, while the effect of endogenous factors might be masked. In contrast, in the thoracic region, mechanical stress on the intervertebral discs is reduced because the region is stabilized by the thoracic cage. Distinct associations among DD in the cervical, thoracic, and lumbar regions might indicate the effects of HT, DL, and IGT on DD are due to endogenous factors. To clarify risk factors for DD, particularly endogenous risk factors, it may be useful to examine associations in not only the cervical and lumbar regions, but in the thoracic region as well.

Study limitations

This study has several limitations. First, this was a cross-sectional study; thus, the causal relationships between MS components and DD remain unclear. These can only be ascertained by a follow-up study that clarifies the incidence and/or progression rates of DD in the same cohort. Second, the participants included in the present study may not represent the general population since they were recruited from only 2 local areas. To confirm whether the participants are representative of the Japanese population, we compared anthropometric measurements and frequencies of smoking and alcohol consumption between the general Japanese population and the study participants. No significant difference in BMI was observed (men: 24.0 kg/m^2 vs. 23.7 kg/m^2, p = 0.33; women: 23.5 kg/m^2 vs. 23.1 kg/m^2, p = 0.07). Further, the proportion of men who smoked and who consumed alcohol (those who regularly smoked or consumed alcohol more than once per month) and the proportion of women who consumed alcohol were significantly higher in the general Japanese population than in the study population, whereas there was no significant difference in the proportion of women who smoked (men who smoked: 32.6% vs. 23.3%,

$p = 0.015$; women who smoked: 4.9% vs. 3.5%, $p = 0.50$; men who consumed alcohol: 73.9% vs. 57.5%, $p < 0.0001$; women who consumed alcohol: 28.1% vs. 18.2%, $p < 0.0001$). These results suggest the likelihood that, in this study, participants had healthier lifestyles than those of the general Japanese population [28]. This "healthy" selection bias should be taken into consideration when generalizing the results obtained from the Wakayama Spine Study. In addition, since the blood samples obtained were not always from participants under fasting conditions, we used serum HDL-C level <40 mg/dL, and not TG level, to indicate DL, and serum HbA1c level ≥5.5%, and not blood glucose level, to indicate IGT, which are indices used by the National Health and Nutrition Survey in Japan [28]. These differences in the definition of MS might have skewed the true association between MS and DD.

Conclusions

We investigated the associations between MS components and DD in the cervical, thoracic, and lumbar regions in a large population of individuals ranging in age from 21 to 97 years. We revealed that OW was significantly associated with presence of DD in the entire spine, and that HT and IGT were significantly associated with presence of DD in the thoracic region. We also found that subjects with 1 or more MS components had a higher OR for presence of DD compared with those without MS components. The prevention of MS may be useful for avoiding DD. Further investigations, along with continued longitudinal surveys of the Wakayama Spine Study, will elucidate the associations between MS components and occurrence or progression of DD.

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Author Contributions

Conceived and designed the experiments: MT NY HH SM HY HO AM YI K. Nagata RK ST HK K. Nakamura TA MY. Performed the experiments: MT NY HH SM HY HO YI K. Nagata RK TA. Analyzed the data: MT NY HH SM HO. Contributed reagents/materials/analysis tools: MT NY HH SM. Wrote the paper: MT.

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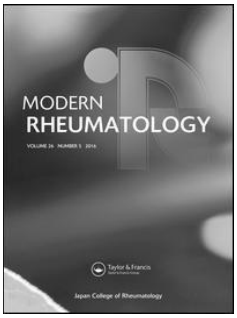

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ORIGINAL ARTICLE

Prevalence of hand osteoarthritis and its relationship to hand pain and grip strength in Japan: The third survey of the ROAD study

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Abstract

Objectives: To examine the prevalence and pattern of hand osteoarthritis (HOA), and determine its relationship with grip strength and hand pain.
Methods: Among the participants of the third survey of the Research on Osteoarthritis/Osteoporosis Against Disability (ROAD) study, 507 Japanese men and 1028 Japanese women were included. Radiographs of both hands were graded for osteoarthritis (OA) using the modified Kellgren–Lawrence (KL) scale. HOA was defined as the presence of at least one affected joint. The absence or presence of subchondral erosion was also scored.
Results: The prevalence of HOA (KL grade $\geq$2) was 89.9% in men and 92.3% in women ($p = 0.11$), and it was significantly associated with age. OA in the distal interphalangeal (DIP) joint was the highest overall. After adjusting for age, sex, body mass index, and the residing area, both severity (KL grade $\geq$3) and erosion were significantly related to low grip strength and hand pain. With regard to the joint groups, severe OA in the DIP and first carpometacarpal joints were related to hand pain.
Conclusion: This study showed a high prevalence of radiographic HOA and a significant relationship between hand pain and the severity of HOA, in addition to erosion.

Keywords

Erosion; Hand, Osteoarthritis, Population-based, Prevalence

History

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Introduction

Hand osteoarthritis (HOA) is one of the most common degenerative joint diseases in the elderly throughout the world. It causes chronic pain and functional disabilities that lead to serious problems in one's daily life [1–3]. Moreover, joint swelling and deformities, such as Heberden or Bouchard nodes, may cause serious cosmetic issues, especially in middle-aged women. However, HOA has not received attention until recently because its clinical burden was extremely underestimated. As a result, the pathogenesis of HOA has largely remained unknown. The reported prevalence of radiographic or symptomatic HOA differs considerably among previous population-based epidemiologic studies [2–10]. This may be due to a limitation in the sample size or variabilities in age, ethnicity, or the definition of HOA. In addition, there are few large-scale population-based cohort studies on the prevalence of HOA in Asia [7].

Hand pain is one of the main symptoms of HOA, yet the association of HOA with pain remains controversial [1,11]. In addition, the relationship between HOA and grip strength remains unclear [1,12]. One of the reasons for this may be that in previous studies, the severity of HOA was not examined, despite the fact that the severity of HOA may be important for pain or grip strength. Thus, in the present study, we examined the association of hand pain or grip strength using a Kellgren–Lawrence (KL) grade $\geq$2 HOA and a KL $\geq$3 HOA.

In addition, the idea of erosive HOA has received more attention in recent years. Erosive HOA was defined as a specific subgroup of HOA with subchondral erosion and cortical destruction [13]. This was first described by Peter et al. in 1966 [14], but there were few population-based studies on erosive HOA [10,15–17]. It is still unknown whether erosive HOA is a separate disease entity or a severe form of HOA [18].

This study aimed to (1) examine the prevalence, pattern, and severity of radiographic HOA in addition to erosive HOA in the general Japanese population and (2) determine the associations between the severity of HOA and hand pain or grip strength, as well as erosive HOA.

Materials and methods

Participants

The Research on Osteoarthritis/Osteoporosis Against Disability (ROAD) study was a nationwide prospective study on bone and

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joint diseases that consisted of population-based cohorts in three communities in Japan: an urban region in Itabashi, Tokyo; a mountainous region in Hidakagawa, Wakayama; and a coastal region in Taiji, Wakayama. Details of the study have been described previously [19,20]. Briefly, residents of these regions were recruited from the resident registration lists. Three thousand forty inhabitants (1061 men and 1979 women) with a mean age of 70.3 years were included in the first survey, which was administered from 2005 to 2007. The study was approved by the ethics committees of the University of Tokyo and the Tokyo Metropolitan Institute of Gerontology. Written informed consent was provided by all participants.

The third survey of the ROAD study was administered during 2012–2013. All participants who attended the first and the second surveys were invited to the follow-up survey. In addition, inhabitants aged $\geq$60 years and residing in the urban area and those aged $\geq$40 years and residing in the mountainous and coastal areas who were willing to respond to the survey were included. As a result, 2566 subjects participated in the third visit. In the present study, we used data from the 1535 participants in the mountainous and coastal regions who underwent radiography for both hands after excluding 27 people who had a history of rheumatoid arthritis (RA) or took medication for RA, based on their responses to an interviewer-administered questionnaire. All of the participants included in the study were Japanese.

All participants completed an interviewer-administered questionnaire that included information on their medical history, family history, physical activity, joint pain, etc. Those who responded that they had pain in any part of their right or left hand $\geq$ 1 day were regarded as people who had hand pain. We also measured the participants' height and weight, and their body mass index (BMI) was calculated. Grip strength was measured using a Toei Light handgrip dynamometer (Toei Light Co., Ltd., Saitama, Japan). Grip strength of both hands was measured, and the dominant hand value was used in the analyses. The dominant hand was defined as the hand that is mainly used in daily life (e.g. the hand that commonly does the writing or uses chopsticks and scissors). When we measured grip strength, we asked the participants which hand was their dominant hand.

Radiographic assessment

Anterior–posterior radiographs of both hands were taken for each patient by licensed radiography technicians using standard radiographic techniques. The radiographs were read by one orthopedist (RK). The second to fifth distal interphalangeal (DIP), proximal interphalangeal (PIP), first to fifth metacarpophalangeal (MCP), thumb interphalangeal (IP), and first carpometacarpal (CMC) joints for each hand were graded for osteoarthritis (OA) using the modified KL scale [21], which was used in Framingham and other studies, to assess the existence and severity of osteophytes, joint space narrowing, sclerosis, and erosion [10]. The modified KL scale was graded from 0 to 4, where 0 is no OA; 1 is questionable osteophytes (OPs) and/or joint space narrowing (JSN); 2 is definite small OPs and/or mild JSN; 3 is moderate OPs and/or moderate JSN, sclerosis, and erosions may be present; and 4 is large OPs and/or severe JSN, sclerosis, and erosions may be present. Subchondral erosion, the characteristic central erosion and associated pseudowidening, was also scored for its absence or presence in the DIP, PIP, and first CMC joints according to the atlas by Altman et al. [22].

Radiographic OA was defined as a KL grade $\geq$2. Severe OA was defined as a KL grade $\geq$3. HOA or severe HOA at the individual level was defined by the presence of at least one affected joint. Hand-joint groups were similarly defined by the presence of at least one affected joint. The presence of subchondral erosion was defined as erosive HOA.

To investigate the intra-observer reliability of the scale, 20 randomly selected hand radiographs were scored by the same reader, and two orthopedists (RK and HO) also scored the 20 radiographs to assess the inter-observer reliability. The intra- and inter-observer reliability was assessed by the κ statistic, and they were 0.78 and 0.77, respectively.

Statistical analysis

The prevalence of HOA for each joint, the joint groups, and the entire hand was compared between sexes using the Chi-square test. Univariate and multivariate logistic regression analyses were used to examine the association between age, sex, BMI, the residing area, grip strength, and hand pain with HOA, severe HOA, or erosive HOA. Univariate and multivariate regression models were used to analyze the effects of each joint group on hand pain or grip strength. A p value <0.05 was used to indicate a significant difference. All the analyses were performed using JMP, version 11.0 (SAS Institute Inc., Cary, NC).

Results

The characteristics and clinical outcomes of the 1535 participants are shown in Table 1. The mean (standard deviation) age was not significantly different between the sexes. More than 90% of subjects were right-hand dominant. The prevalence of radiographic HOA (KL grade $\geq$2) in at least one joint among all the joints was >90% in both sexes, and there was no significant difference between the sexes. The prevalence of severe HOA (KL grade $\geq$3) was approximately 40%, but there was no difference between the sexes.

Figure 1 shows the prevalence of HOA and the severity of HOA classified by age and sex. Both were significantly associated with age ($p < 0.05$) in both sexes, and nearly 100% of men and women >70 years had at least one radiographic HOA joint.

The prevalence of OA at the joint level is shown in Table 1. The prevalence of OA was the highest in the DIP joints, followed by the thumb IP, PIP, first CMC, and MCP joints. Figure 2 shows the prevalence of OA observed in each hand joint in men and women in detail. Numbers on the left side show the prevalence of OA in men, and those of the right side show the prevalence of OA in women. OA of the DIP joint occurred more frequently in women than in men ($p < 0.05$). OA in the PIP joint also tended to occur more in women than in men, but only the right fifth, left fourth, and fifth PIP joints had significantly more OA in women than in men ($p < 0.05$). In contrast, regarding the MCP joints, OA in the right third and fourth as well as the left second and third MCP joints was more common in men than in women ($p < 0.01$).

The prevalence of HOA classified by the dominant and non-dominant hands is shown in Table 2. The first to third MCP joints with OA were significantly more frequent in the dominant hand (all, $p < 0.0001$). In contrast, the prevalence of the fifth PIP and first CMC joints with OA was higher in the non-dominant hand than in the dominant hand ($p = 0.0055$ and 0.0016, respectively).

Regarding erosive HOA, all the people who had more than one joint of erosive HOA were included in the group of severe HOA. They accounted for 10.6% of people who had severe HOA. The prevalence of erosive HOA was higher in women than in men ($p < 0.01$) (Table 1).

Table 1 also shows the prevalence of hand pain. When comparing the high prevalence of HOA, the prevalence of hand pain was smaller in both sexes, and there were no significant differences between the sexes. Hand pain was not significantly

Table 1. Participants' characteristics and the clinical outcomes of hand osteoarthritis.

	Total ($n = 1535$)	Men ($n = 507$)	Women ($n = 1028$)	p value (Men versus Women)
Age, years	65.6 ± 13.0	66.3 ± 13.7	65.3 ± 12.6	0.19
BMI, kg/m^2	23.0 ± 3.6	23.6 ± 3.5	22.7 ± 3.6	<0.0001
Residing in the coastal area, %	54.4	48.3	44.3	0.14
Dominant hand (right), %	94.2	92.3	95.1	0.030
Dominant hand grip strength, kg	30.4 ± 9.9	40.5 ± 9.0	25.5 ± 5.8	<0.0001
Radiographic HOA (≥1 joint)	91.5	89.9	92.3	0.11
DIP (2–5) OA	85.5	84	86.3	0.24
PIP (2–5) OA	57.5	50.9	60.7	0.0003
Thumb IP OA	64.2	63.5	64.6	0.68
MCP (1–5) OA	38.2	39.8	37.5	0.36
First CMC OA	50.2	50.5	50	0.86
Severe HOA (≥1 joint)	39.8	37.3	41.1	0.16
Erosive HOA (≥1 joint)	4.2	2.2	5.3	0.0048
Number of HOA joints (KL ≥2)	9.3	8.7	9.6	0.014
Hand pain, %	7.4	5.7	8.2	0.096

BMI, body mass index; HOA, hand osteoarthritis; DIP, distal interphalangeal; PIP, proximal interphalangeal; IP, interphalangeal; MCP, metacarpophalangeal; CMC, carpometacarpal.

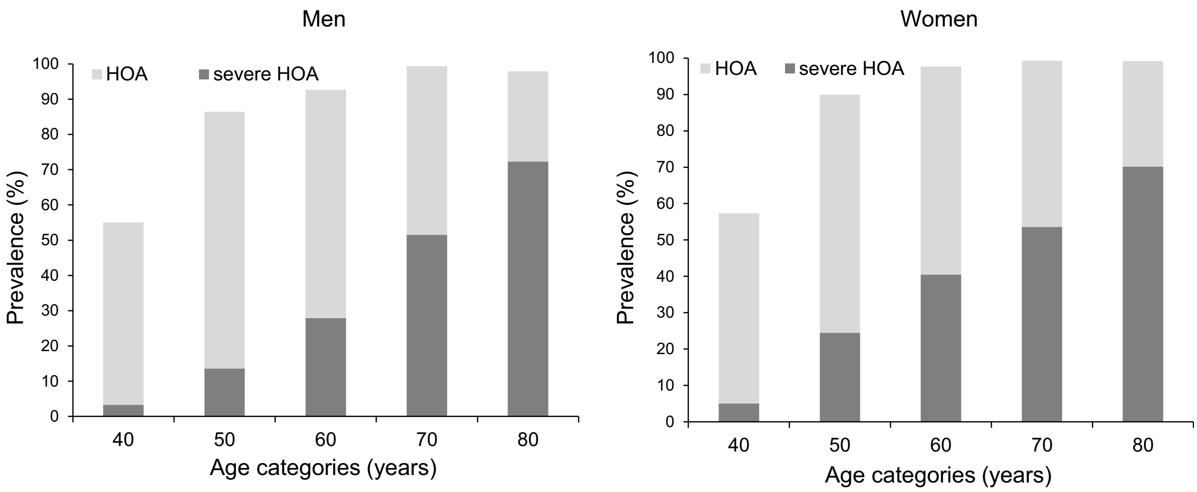

Figure 1. Prevalence of radiographic hand osteoarthritis (HOA) and severe HOA in both sexes among the age categories.

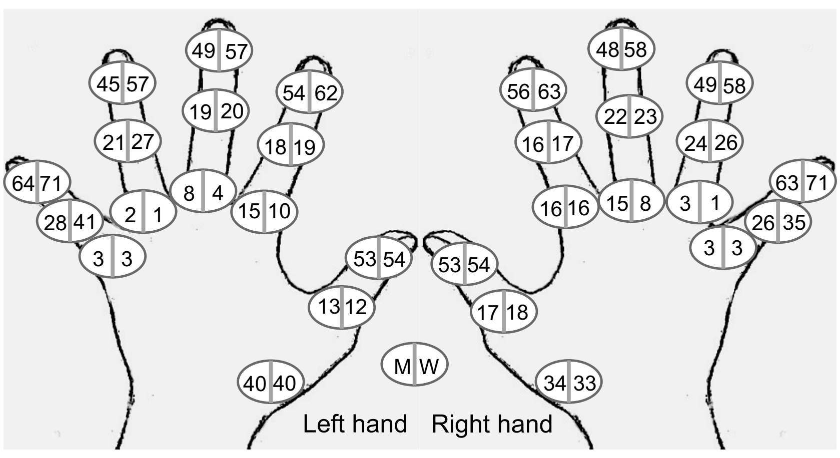

Figure 2. Prevalence (%) of radiographic hand osteoarthritis in each joint in men (M, left) and women (W, right).

different between the dominant and non-dominant hands (Table 2).

Table 3 shows the factors related to the prevalence of HOA, severe HOA, and erosive HOA. Multivariate logistic regression analysis showed that age was significantly associated with HOA and severe HOA; however, sex had no association with them. A higher BMI was significantly related to HOA, but it had no relationship with severe HOA. After adjusting for age, sex, BMI, and the residing area, HOA had no relationship with grip strength or hand pain. Conversely, severe HOA was significantly related to a low grip strength and hand pain compared with non-severe HOA ($KL \leq 2$). To clarify the relationship between hand pain and the severity of HOA, we categorized HOA in three groups: $KL \leq 1$, $KL = 2$, and $KL \geq 3$ HOA. Only severe HOA ($KL \geq 3$) was significantly related to hand pain (Table 4).

Age, sex, and BMI were not significantly related to erosive HOA in multivariate logistic regression analysis (Table 3). However, there was a significant relationship between erosive HOA and low grip strength, and hand pain. As severe HOA and erosive HOA were related to hand pain, we separated those who had a $KL \geq 3$ with erosive HOA and those who had a $KL \geq 3$ without erosive HOA. Compared to those with a $KL \leq 1$, both erosive HOA and a $KL \geq 3$ without erosive HOA were significantly related to hand pain after adjusting for age, sex, BMI, the residing area, and grip strength ($p = 0.0001$). Moreover, the odds ratio (OR) for erosive HOA was much higher (OR: 10.25; 95% confidence interval [CI]: 3.07–41.28) than that of a $KL \geq 3$ without erosive HOA (OR: 4.13; 95% CI: 1.42–15.27). When classified based on the KL grade and the presence of erosive HOA, the prevalence of hand pain in the erosive HOA group was much higher than that of the other types ($p < 0.0001$) (Figure 3).

We also examined factors associated with hand pain, and found that hand pain was related to low grip strength ($p = 0.0051$) (Table 4). The association of hand pain with OA in the DIP, PIP,

Table 2. Comparison of the prevalence of hand osteoarthritis (HOA) and hand pain between the dominant and non-dominant hands.

	Dominant hand	Non-dominant hand	*p* value
Radiographic HOA (≥1 joint), %	87.8	86.7	0.30
DIP5	69.1	68.4	0.67
DIP4	55.3	52.6	0.14
DIP3	55.2	53.8	0.44
DIP2	61.1	58.6	0.17
PIP5	32.5	37.3	0.0055
PIP4	25.3	24.9	0.77
PIP3	22.3	20.1	0.13
PIP2	16.6	19.0	0.080
MCP5	2.7	3.1	0.59
MCP4	1.8	1.4	0.31
MCP3	10.8	4.9	<0.0001
MCP2	16.0	11.1	<0.0001
Thumb IP	53.9	53.1	0.66
MCP1	17.7	11.7	<0.0001
CMC1	34.0	39.5	0.0016
Hand pain	5.2	4.0	0.12

DIP, distal interphalangeal; PIP, proximal interphalangeal; MCP, metacarpophalangeal; IP, interphalangeal; CMC, carpometacarpal.

Table 3. Factors related to the prevalence of hand osteoarthritis (HOA), severe HOA, and erosive HOA.

	HOA (KL ≥ 2)		Severe HOA (KL ≥ 3)		Erosive HOA	
	Crude OR (95% CI)	Adjusted OR (95% CI)	Crude OR (95% CI)	Adjusted OR (95% CI)	Crude OR (95% CI)	Adjusted OR (95% CI)
Age (+1 year)	1.14** (1.12–1.16)	1.15** (1.12–1.17)	1.09** (1.08–1.10)	1.08** (1.06–1.09)	1.05** (1.03–1.08)	1.02 (0.99–1.05)
Sex (reference: men)	1.34 (0.93–1.94)	3.18** (1.45–6.94)	1.17 (0.94–1.46)	0.93 (0.62–1.39)	2.50** (1.35–5.08)	0.77 (0.33–1.92)
BMI (+1 kg/m^2)	1.09** (1.04–1.16)	1.11** (1.04–1.19)	1.00 (0.97–1.03)	1.02 (0.99–1.05)	0.93 (0.86–1.01)	0.95 (0.88–1.03)
Residing area (reference: mountainous)	0.78 (0.54–1.12)	1.34 (0.86–2.08)	0.53** (0.43–0.65)	0.68** (0.53–0.85)	0.81 (0.49–1.33)	0.96 (0.57–1.62)
Grip strength (+1 kg)	0.95** (0.93–0.97)	1.03 (1.00–1.07)	0.94** (0.93–0.95)	0.97* (0.95–0.99)	0.89** (0.86–0.92)	0.90** (0.86–0.95)
Hand pain	2.65* (1.09–8.74)	1.85 (0.69–6.54)	2.01** (1.37–2.96)	2.23** (1.45–3.45)	3.80** (1.97–6.93)	3.56** (1.79–6.73)

The adjusted odds ratios (ORs) were calculated using multivariate logistic regression analysis.
BMI, body mass index; CI, confidence interval; KL, Kellgren–Lawrence grade.
*$p < 0.05$.
**$p < 0.01$.

Table 4. Factors related to hand pain.

	Crude OR (95% CI)	*p* value	Adjusted OR (95% CI)	*p* value
Age (+1 year)	1.01 (0.99–1.02)	0.36	0.97 (0.95–1.00)	0.020
Sex (reference: men)	1.47 (0.96–2.30)	0.078	0.67 (0.35–1.34)	0.025
BMI (+1 kg/m^2)	1.06 (1.00–1.11)	0.032	1.07 (1.01–1.12)	0.014
Residing area (reference: mountainous)	1.24 (0.84–1.84)	0.28	1.36 (0.91–2.05)	0.13
Grip strength (+1 kg)	0.97 (0.95–0.99)	0.0027	0.95 (0.92–0.98)	0.0051
HOA				
KL ≤ 1 HOA	1 (reference)		1 (reference)	
KL = 2	1.94 (0.77–6.51)	0.17	2.30 (0.85–8.14)	0.11
KL ≥ 3 HOA	3.62 (1.46–12.08)	0.0035	4.82 (1.67–17.69)	0.0024

The adjusted odds ratios (ORs) were calculated using multivariate logistic regression analysis.
BMI, body mass index; HOA, hand osteoarthritis; CI, confidence interval.

MCP, thumb IP, and first CMC joints was examined separately, and the DIP and first CMC joints with severe OA were found to have a significant association with hand pain ($p = 0.010$ and $p = 0.0043$) (Table 5). With regard to grip strength, severe OA of any joint group was significantly related to low grip strength after adjusting for age, sex, BMI, the residing area, and hand pain (all, $p < 0.01$).

Discussion

This is the first population-based study to examine the prevalence and patterns of HOA in Japanese men and women in detail. This study showed a high prevalence of radiographic HOA in Japanese elderly and a relationship between the HOA severity and hand pain, and low grip strength. We also found that age and BMI were related to HOA. With regard to the joint groups, the DIP and first CMC joints with severe OA were related to hand pain. We also showed the prevalence of erosive HOA in this Japanese population and found that hand pain was significantly related to erosive HOA. Hand pain was also related to low grip strength.

In the present study, the prevalence of radiographic HOA was 89.9% in men and 92.3% in women, which are much higher than those reported in previous studies in the United States, Europe, and Asia [2,5–10]. As there may be some differences in the participants' number, age distribution, or sex ratio, we cannot compare the prevalence among cohorts directly. However, it may be suggested that ethnicity is the main cause of the difference in the prevalence among the studies. We previously showed that the prevalence of knee OA in our cohorts was much higher than that in Caucasians [20]. Japanese individuals may have a high prevalence of OA in the knee and hand joints.

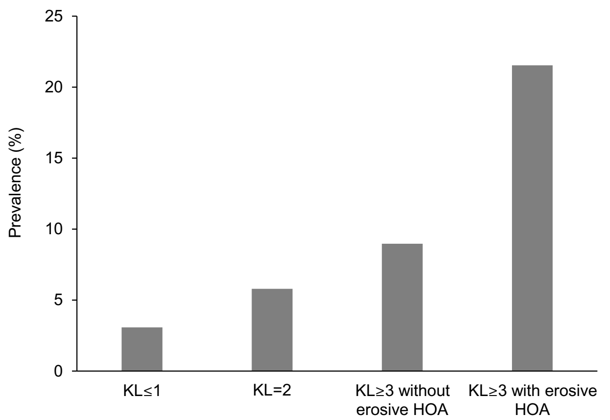

Figure 3. Prevalence (%) of hand pain in each subgroup classified by the Kellgren–Lawrence (KL) grade and the presence of erosive hand osteoarthritis (HOA).

The association between HOA and hand pain remains controversial. Zhang et al. reported that the severity of HOA is related to hand pain, although the details were not described [1]. Dahaghin et al. reported that radiographic HOA was a poor explanation for hand pain ($R^2 = 0.005$) in a multivariate model from the Rotterdam study [11]. In the present study, we focused on KL grade $\geq$2 HOA and severe HOA (KL $\geq$ 3), and we found that although there was no significant relationship between KL grade $\geq$2 HOA and hand pain, or grip strength, severe HOA had a significant relationship with these variables according to the multivariate logistic model. The severity of HOA may be important for hand pain or low grip strength. Few studies have focused on the relationship between the severity of HOA and hand pain or disabilities [1]. We also determined the relationship between hand pain and low grip strength after adjusting for other factors. Zhang et al. reported that subjects with symptomatic HOA had reduced maximal grip strength (by 10%) [1]. As our study was a cross-sectional one, we could not confirm causality between low grip strength, hand pain, and the severity of HOA. Our future longitudinal study will be able to clarify the relationship among these factors.

We also examined erosive HOA, which was defined as the presence of subchondral erosion. To the best of our knowledge, this is the first large-scale cohort study to show the prevalence of erosive HOA in Asia, and we found discrepancies between erosive HOA and HOA, as defined by the KL grade. First, although the prevalence of KL grade $\geq$2 HOA in the present study was much higher than that in previous studies, the prevalence of erosive HOA in the present study was similar to that in previous studies [10,15,16]. This indicates that erosive HOA may have a distinct aetiology from severe HOA because if erosive HOA is a severe form of HOA, the percentage of erosive HOA of HOA in our cohort should be larger than those of other cohorts. Second, although the prevalence of severe HOA was significantly associated with age, we could not find a significant relationship between age and erosive HOA, which may also indicate the distinct aetiology between erosive HOA and severe HOA. In fact, erosive HOA was associated with several genetic factors [23,24]. Third, we also found a strong relationship between erosive HOA and hand pain, which may indicate that erosion was more strongly related to hand pain than the severity of HOA. Previous studies have shown that the prevalence of hand pain was significantly higher in subjects with erosive HOA than in those without erosive HOA [10,15,16], but no study has analyzed the severity of HOA and erosive HOA separately. As all the erosive HOA cases were included in severe HOA, we could not thoroughly conclude that erosive HOA was not a severe form of HOA; however, there may be different aetiologies between severe HOA with and without erosion.

The pattern of joint involvement in our cohorts was different from that of other studies. Caucasians had the highest prevalence of OA in the first CMC joints, but the prevalence of first CMC joints with OA was the second lowest in the present study [10]. A former population-based cohort study in Japan with a small sample

Table 5. Association between hand pain and severe hand osteoarthritis in the joint groups.

	Crude OR (95% CI)	*p* value	Adjusted OR (95% CI)	*p* value
DIP joint	1.78 (1.20–2.63)	0.0041	1.76 (1.15–2.70)	0.010
PIP joint	1.75 (0.98–2.94)	0.058	1.58 (0.86–2.76)	0.13
MCP joint	0.29 (0.015–1.85)	0.059	2.51 (0.96–5.81)	0.059
Thumb IP joint	0.88 (0.45–1.57)	0.68	0.85 (0.42–1.58)	0.62
First CMC joint	2.41 (1.42–3.94)	0.0016	2.31 (1.30–3.92)	0.0043

Adjusted odds ratios (ORs) were calculated using multiple logistic regression analysis after adjusting for age, sex, body mass index, the residing area, and dominant hand grip strength.

DIP, distal interphalangeal; PIP, proximal interphalangeal; MCP, metacarpophalangeal; IP, interphalangeal; CMC, carpometacarpal; CI, confidence interval.

size also showed that the prevalence of OA at the first CMC joint was less in the Japanese cohort than in American women (OR: 0.15; 95% CI: 0.11–0.22) [4]. This may be partly explained by environmental factors (e.g. using chopsticks, which is part of the Japanese lifestyle). In fact, Hunter et al. reported that the prevalence of OA in the thumb IP and second and third PIP and MCP joints in the hands that used the chopsticks was higher than that in hands that did not use the chopsticks [25]. Hand pain was related to severe OA in the DIP and first CMC joints. This result is comparable to that of the Framingham study, which noted that the prevalence of symptomatic OA was higher in the DIP, PIP, and first CMC joints [1].

We also found that BMI was related to HOA. As hand joints are not weight-bearing joints, the relationship between BMI and HOA cannot only be explained by mechanical factors; thus, some metabolic factors may influence HOA. In fact, there were connections between adipokines and knee OA, independently of animal weight [26]. Yusuf et al. reported that adiponectin levels were associated with the progression of HOA [27]. HOA may also be explained by these adipokines, which influence the joint cartilage. As we have collected the participants' blood samples and the interviewer-administered questionnaires that include nutritional information, further analyses may reveal the relationship between HOA and BMI.

The present study has several limitations. First, there was some selection bias in our cohort because we excluded those who could not come to the survey site and those who could not understand or sign informed consent form [19]. Second, although we used the same radiographic atlas and definition that former studies had used to read our radiographs, strict comparisons among our results and other studies may be limited because of the differences in readers [1,21,22]. Third, we assessed the first CMC joints using anterior–posterior radiographs of the hand. Strictly speaking, it may have been better to use lateral view radiographs to assess OA in the first CMC joints [28]. However, the intra- and inter-observer reliability for the first CMC joints in our study was not bad (0.70 and 0.64, respectively). Furthermore, in previous cohort studies, the anterior–posterior view was used to assess OA in all of the hand joints [1,2,4,5,7,8]; thus, comparing the prevalence of OA among them might be useful.

In conclusion, the present study showed a high prevalence of radiographic HOA in the Japanese elderly. Severe HOA defined as KL grade ≥ 3 was significantly related to grip strength and hand pain. In addition, hand pain had a relationship with severe HOA, particularly in the DIP and first CMC joints. We also showed the prevalence of erosive HOA and found a strong relationship between erosive HOA and hand pain. Further studies, along with continued longitudinal surveys from the ROAD study, will help to elucidate the environmental backgrounds of HOA, including erosive HOA and its relationship to hand pain or grip strength.

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Conflict of interest

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Patient Satisfaction with Posterior Decompression Surgery for Cervical Ossification of the Posterior Longitudinal Ligament: Prognostic Radiographic Factors and Patient-Reported Outcomes for the Effectiveness of Surgical Treatment

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■ OBJECTIVE: **To identify the prognostic factors associated with patient satisfaction after double-door laminoplasty for cervical compression myelopathy due to ossification of the posterior longitudinal ligament (OPLL).**

■ METHODS: **The study group comprised 44 patients (30 males and 14 females) with OPLL who underwent double-door laminoplasty at our institution with a minimum follow-up of 1 year. The mean patient age was 63.8 years (range, 48–86 years). We evaluated the patients' postoperative satisfaction using a questionnaire and divided them into 2 groups, satisfied and dissatisfied. We assessed various radiographic parameters. The patient-reported outcomes, including the Short Form-36 Physical Component Summary (SF-36 PCS), Neck Disability Index, neck pain, arm pain, and Japanese Orthopedic Association Cervical Myelopathy Evaluation Questionnaire (JOACMEQ), were assessed and used to evaluate the effectiveness of surgical treatment according to the concept of minimum clinically important difference (MCID).**

■ RESULTS: **The satisfied group comprised 29 patients (65.9%). The dissatisfied group had a higher percentage of hill-shaped ossifications compared with the satisfied group (46.7% vs 17.2%; $P = 0.04$). The satisfied group had a higher proportion of patients with SF-36 PCS reaching the MCID threshold value (81.8% vs 14.3%; $P < 0.01$) and with effective surgical treatment as evaluated by the JOACMEQ lower extremity function domain (61.5% vs 10.0%; $P < 0.01$).**

■ CONCLUSION: **Patient satisfaction after laminoplasty was insufficient in patients with a hill-shaped ossification. The patients with OPLL who were able to recognize a difference in their clinical physical function, especially lower extremity function, were satisfied after laminoplasty.**

INTRODUCTION

Ossification of the posterior longitudinal ligament (OPLL), characterized by progressive heterotopic ossification within the spinal ligament, has been recognized as an important pathology causing cervical compressive myelopathy not only in Asian populations, but also in Europe and North America.[1,2] Although the main treatment for cervical myelopathy caused by OPLL is surgery, several unique characteristics of this disorder make the appropriate surgical approach controversial. The advantages of an anterior approach are that the excision of OPLL enables direct decompression of the spinal cord, and that spinal fusion can immobilize dynamic factors to maintain a suitable

Key words
- Cervical myelopathy
- Laminoplasty
- Minimum clinically important difference
- Ossification of the posterior longitudinal ligament
- Patient satisfaction
- Surgical outcome

Abbreviations and Acronyms
BF: Bladder function
CF: Cervical spine function
HRQOL: Health-related quality of life
JOACMEQ: Japanese Orthopedic Association Cervical Myelopathy Evaluation Questionnaire
LEF: Lower extremity function
MCID: Minimum clinically important difference
NDI: Neck Disability Index
OPLL: Ossification of the posterior longitudinal ligament
PRO: Patient-reported outcome
QOL: Quality of life
SCB: Substantial clinical benefit
SF-36 PCS: Short Form-36 Physical Component Summary
UEF: Upper extremity function

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cervical alignment; however, this approach is technically demanding and has a higher potential risk of complications, such as nonunion, graft dislodgment, dural tear, and neurologic deterioration.[3-5] In contrast, a posterior approach, such as laminoplasty, is a relatively safe technique that can cope with multisegmental OPLL and comorbid developmental spinal canal stenosis. Nonetheless, there have been some cases with limited surgical outcomes after laminoplasty, and several risk factors for a poor surgical outcome also have been reported, including kyphotic cervical alignment,[6,7] severe occupation of the spinal canal,[6-10] hill-shaped ossification,[9] negative K-line,[11] intramedullary high signal intensity,[6,10,12] and dynamic factors, such as hypermobility of the cervical spine.[12-14]

Patient-reported outcomes (PROs) and health-related quality of life (HRQOL) are becoming the main outcomes used in rigorous studies of the efficacy of treatment after spinal surgery. Recent studies have focused on the patients' viewpoints and the finite medical resources. Research using the concept of the minimum clinically important difference (MCID) has been increasingly performed to reassess the efficacy of spinal surgery.[15-21] Because the MCID indicates the smallest change in an outcome measure that reflects a clinically meaningful improvement for patients,[15,22] surgical treatment for spinal disorders able to reach MCID threshold values justifies its incorporation into clinical practice.[19] Therefore, based on this trend, the efficacy of laminoplasty for cervical compressive myelopathy due to OPLL should be reevaluated based on assessment using PROs, HRQOL, and the MCID.

Although several studies on self-reported postoperative satisfaction after laminoplasty in patients with cervical compressive myelopathy have been reported to date,[23-26] none of these has investigated prognostic radiographic factors, which are reportedly important factors affecting the choice of surgical options for patients with OPLL,[7-14] with regard to PROs. The aim of this retrospective study was to identify the prognostic factors associated with patient satisfaction after double-door laminoplasty for cervical compression myelopathy due to OPLL.

METHODS

Data Source

We retrospectively reviewed all patients with OPLL who underwent double-door laminoplasty between April 2003 and November 2013 in our institution and who completed both preoperative and postoperative questionnaires. The minimum duration of follow-up was 1 year. Patient characteristics and perioperative surgical data were obtained from medical charts. The patients without myelopathy who underwent surgical treatment with an expectation of improved radiculopathy were excluded from the study. Patients with acute spinal cord injury were excluded as well. In addition, 2 patients with OPLL undergoing laminoplasty during the observation period were excluded because they were lost to follow-up. Informed consent was obtained from each patient, and the study was approved by the Institutional Review Board of The University of Tokyo.

Regarding surgical treatment for the patients with OPLL, surgeons used their preferred surgical method according to individual patient characteristics.

Double-Door Laminoplasty

We performed double-door laminoplasty as described previously.[26,27] The cervical laminae were exposed laterally to the medial aspect of the facet joints, and the interspinous ligaments were removed. The spinous processes were split sagittally. Once bilateral gutters for the hinges were carefully created at the transitional area between the facet joint and laminae, spinal canal enlargement was achieved via a bilateral opening of the laminae. HA spacers (Boneceram; Olympus Terumo Biomaterials, Tokyo, Japan) were placed between the opened laminae and fixed with nonabsorbable sutures. The patient wore a soft cervical orthosis for approximately 3 weeks after the surgery.

Radiographic Parameters

All patients underwent radiography, computed tomography (CT), and magnetic resonance imaging (MRI) preoperatively. In the postoperative period, radiographs were obtained routinely at each follow-up visit. Postoperative MRI was performed several weeks after surgery once patient consent was obtained.

Based on the preoperative findings from standard lateral radiographs, the OPLL type, OPLL shape, C2—C7 angle, and K-line were evaluated. OPLL was classified into 4 types: continuous, segmental, mixed, and other (circumscribed or localized).[28-30] According to a previous report on the sagittal shape of the ossified lesion,[9] the presence of a hill-shaped OPLL was specified. When the C2—C7 angle had a positive value, this meant that the cervical alignment was lordotic. A C2—C7 angle $<-5°$ was considered to indicate the presence of kyphosis.[10] The K-line was defined as the straight line connecting the midpoints of the spinal canal at C2 and C7; a negative K-line meant that the OPLL exceeded the K-line and grew beyond it.[11] We used preoperative sagittal CT of the cervical spine to measure the ratio of OPLL occupying the canal, which was calculated as the ratio of the maximum anteroposterior thickness of the OPLL to the anteroposterior diameter of the spinal canal at the corresponding level. A value $>60\%$ was defined as a severe occupying ratio.[9] The presence of intramedullary high intensity in the spinal cord was assessed using preoperative T2-weighted MRI of the cervical spine.

Postoperative radiographic evaluations, including the C2—C7 angle and residual anterior compression of the spinal cord, were examined as well. Postoperative kyphosis was defined as a C2—C7 angle $<-5°$. Anterior compression of the spinal cord after laminoplasty was evaluated using postoperative MRI. According to previous reports,[31] the criteria for defining significant were as follows: 1) effacement of anterior cerebral spinal fluid buffer on the T2 sagittal and axial images, and 2) evidence of anterior compression of cord substance on the T1 sagittal and axial images. If both criteria were satisfied, then the MRI findings were considered to indicate the presence of anterior compression of the spinal cord.

PROs

We assessed the preoperative PROs from the questionnaires administered before surgery during hospital admission. The questionnaires included several PROs, including the Neck Disability Index (NDI),[32] the Short Form-36 Physical Component Summary (SF-36 PCS),[33] numeric rating scales of pain in the neck and arms, and the Japanese Orthopedic Association Cervical Myelopathy Evaluation Questionnaire (JOACMEQ).[34] The JOACMEQ was used to evaluate patient-reported neurologic function and HRQOL in 5 areas: cervical spine function (CF), upper extremity function (UEF), lower extremity function (LEF), bladder function (BF), and quality of life (QOL). Postoperatively, questionnaires that included the aforementioned PROs, in addition to the original satisfaction scales that assessed postoperative outcome, were sent to each patient.

Patient satisfaction was evaluated based on a 7-point scale as reported previously[26]: very satisfied, satisfied, slightly satisfied, neither satisfied nor dissatisfied, slightly dissatisfied, dissatisfied, and very dissatisfied. Based on this evaluation, the patients were divided into 2 groups: satisfied (comprising very satisfied, satisfied, and slightly satisfied) and dissatisfied (comprising neither satisfied nor dissatisfied, slightly dissatisfied, dissatisfied, and very dissatisfied). Postoperative PROs were evaluated using the questionnaires administered at the latest follow-up examination.

Assessment of the Effectiveness of Surgical Treatment

We considered that all of the PROs (except the JOACMEQ) that reached the MCID threshold values indicated that the surgical treatment was effective. Based on a previous report,[15] the MCID threshold values for each PRO were set as follows: 7.5 for the NDI, 4.1 for the SF-36 PCS, and 2.5 for arm and neck pain. According to this MCID concept, we defined patients with an 8-point decrease in the NDI, a 4.1-point increase in the PCS, and a 3-point decrease in arm or neck pain as having undergone effective surgical treatment.

Evaluation of the therapeutic effect using the JOACMEQ has been described previously.[34] According to this evaluation, we defined effective surgical treatment for each domain of the JOACMEQ as follows: 1) the posttreatment score was higher than the pretreatment score by $\geq$20 points, and 2) the pretreatment score was $<$90 and the posttreatment score was $\geq$90. Patients with both preoperative and postoperative scores $>$90 were excluded from this analysis.

Assessment of Objective Neurologic Function

We evaluated preoperative baseline cervical compressive myelopathy using the conventional doctor-based Japanese Orthopedic Association (JOA) score.[35]

Statistical Analysis

All PROs and the effectiveness of surgical treatment were compared between the satisfied and dissatisfied groups. Continuous outcomes were compared using a 1-factor analysis of variance, and categorical outcomes were compared using the χ^2 test and Fisher's exact test. The Jonckheere–Terpstra test was used to identify associations between the duration of follow-up and the satisfaction rating. All statistical analyses except the Jonckheere–Terpstra test were performed using JMP PRO version 11 (SAS Institute Japan, Tokyo, Japan). The Jonckheere–Terpstra test was performed using SPSS version 23 (IBM Japan, Tokyo, Japan). The threshold for significance was $P < 0.05$.

RESULTS

The study cohort comprised 44 consecutive patients (30 males and 14 females), with a mean age of 63.8 years (range, 48–86 years). The mean duration of follow-up was 23.8 months (range, 12–89 months). The mean preoperative JOA score was 10.9 points (range, 6–15 points). The most common surgical decompression level was C3–C7 (in 20 patients), followed by C2–C7 (in 16 patients), and C3–T1 (in 3 patients). The patient characteristics and radiographic parameters are presented in Table 1. The mean C2–C7 angle was 6.4° (range, 27° to −27°). The most common type of OPLL was the localized type (34.1%), followed by the continuous type (25.0%) and the mixed type (22.7%). A hill-shaped ossification was seen in 12 patients (27.3%). A negative K-line was seen in 14 patients (31.8%). The mean occupying ratio of ossification was 46.1% (range, 26%–73%). An intramedullary high signal intensity on cervical MRI was seen in 39 patients (88.7%). Postoperatively, the mean C2–C7 angle was 6.8° (range,

Table 1. Baseline and Radiographic Characteristics

Characteristic	Value
Total number of patients	44
Age, years, mean ± SD (range)	63.8 ± 8.3 (48–86)
Sex, male, *n* (%)	30 (68.2)
Follow-up, months, mean ± SD (range)	23.8 ± 14.4 (12–89)
Preoperative JOA score, mean ± SD (range)	10.9 ± 2.2 (6–15)
Decompression level, *n* (%)	
C3–C7	20 (45.5)
C2–C7	16 (35.6)
C3–T1	3 (6.8)
Other	5 (11.4)
Preoperative radiographic parameters	
C2–C7 angle, degrees, mean ± SD (range)	6.4 ± 11.2 (27 to −27)
Type of ossification, *n* (%)	
Continuous	11 (25.0)
Segmental	8 (18.2)
Mixed	10 (22.7)
Others	15 (34.1)
Hill-shaped ossification, *n* (%)	12 (27.3)
K-line (−), *n* (%)	14 (31.8)
Occupation ratio, %, mean ± SD (range)	46.1 ± 10.9 (26–73)
Presence of IHSI on MRI, *n* (%)	39 (88.7)
Postoperative radiographic parameters	
C2–C7 angle, degrees, mean ± SD (range)	6.8 ± 12.1 (33 to −32)
Residual ACS on MRI, *n* (%)	14 (33.3)

JOA, Japanese Orthopedic Association; IHSI, intramedullary high signal intensity; MRI, magnetic resonance imaging; ACS, anterior compression of the spinal cord.

33° to −32°). Among the 42 patients who underwent postoperative MRI, 14 (33.3%) showed residual anterior compression of the spinal cord.

One patient exhibited neurologic deterioration owing to collapse of the cervical lamina at 7 months after the index surgery, necessitating further decompression surgery. No patient experienced any other perioperative complications.

Preoperative and postoperative PROs are summarized in Table 2. Several postoperative PROs, including the SF-36 PCS, arm pain, and all JOACMEQ domains except bladder function, improved significantly compared with preoperative values (from 24.5 ± 17.5 to 34.3 ± 15.4 [$P < 0.01$], from 4.1 ± 3.3 to 2.8 ± 2.6 [$P < 0.01$], from 55.5 ± 35.1 to 64.9 ± 30.6 [$P < 0.01$], from 73.6 ± 21.3 to 84.8 ± 13.3 [$P < 0.01$], from 56.6 ± 25.9 to 72.8 ± 19.6 [$P < 0.001$], and from 44.4 ± 18.0 to 52.5 ± 16.9 [$P = 0.01$], respectively). The mean change between the preoperative and postoperative periods in the SF-36 PCS reached the MCID, whereas the changes in the NDI, arm pain, and neck pain did not reach the MCID.

Overall, the satisfied group comprised 29 patients (65.9%), including 7 patients who were very satisfied, 16 who were satisfied, and 6 who were slightly satisfied. The dissatisfied group comprised the remaining 15 patients (34.1%), including 13 patients who were neither satisfied nor dissatisfied, 1 who was slightly dissatisfied, and 1 who was dissatisfied. No patients reported being very dissatisfied.

A comparison of baseline and radiographic characteristics between the satisfied and dissatisfied groups is shown in Table 3. The baseline data, including age, sex, follow-up period, and preoperative JOA score, did not differ significantly between the 2 groups. Hill-shaped ossifications were present in 5 patients (17.2%) in the satisfied group, compared with 7 patients (46.7%) in the dissatisfied group ($P = 0.04$). The satisfied group had an insignificantly higher proportion of continuous-type OPLL compared with the dissatisfied group (34.5% vs. 6.7%; $P = 0.13$). None of the other radiographic factors, including kyphosis, a negative K-line, a severe occupying ratio, an intramedullary high signal intensity, or anterior compression of the spinal cord, was significantly different between the 2 groups.

We also analyzed the effectiveness of surgical treatment based on each PRO between the 2 groups, as shown in Table 4. Compared with the dissatisfied group, the satisfied group had a higher proportion of patients with the SF-36 PCS reaching the MCID ($P < 0.01$) and a higher level of effective surgical treatment based on the JOACMEQ LEF ($P < 0.01$). The satisfied group had a higher portion of patients with the NDI reaching the MCID compared with the dissatisfied group (50.0% vs. 18.2%), but the difference was not significant ($P = 0.14$). In addition, the satisfied

Table 2. Preoperative and Postoperative Patient-Reported Outcomes

Patient-Reported Outcome	Preoperative	Postoperative	*P* Value	MCID
SF-36 PCS, mean ± SD	24.5 ± 17.5	34.3 ± 15.4	<0.01	Reached
NDI, mean ± SD	30.2 ± 16.1	25.1 ± 16.3	0.09	Not reached
Neck pain, mean ± SD	3.2 ± 3.3	2.8 ± 2.7	0.47	Not reached
Arm pain, mean ± SD	4.1 ± 3.3	2.8 ± 2.6	<0.01	Not reached
JOACMEQ, mean ± SD				
CF	55.5 ± 35.1	64.9 ± 30.6	<0.01	
UEF	73.6 ± 21.3	84.8 ± 13.3	<0.01	
LEF	56.6 ± 25.9	72.8 ± 19.6	<0.001	
BF	70.8 ± 21.2	76.4 ± 19.1	0.15	
QOL	44.4 ± 18.0	52.5 ± 16.9	0.01	
Satisfaction, *n* (%)				
Very satisfied		7 (15.9)		
Satisfied		16 (36.4)		
Slightly satisfied		6 (16.7)		
Neither satisfied nor dissatisfied		13 (29.5)		
Slightly dissatisfied		1 (2.3)		
Dissatisfied		1 (2.3)		
Very dissatisfied		0 (0.0)		

MCID, minimum clinically important difference; SF-36 PCS, Short Form 36 Physical Component Summary; NDI, Neck Disability Index; JOACMEQ, Japanese Orthopedic Association Cervical Myelopathy Evaluation Questionnaire; CF, cervical spine function; UEF, upper extremity function; LEF, lower extremity function; BF, bladder function; QOL, quality of life.

Table 3. Comparison of Baseline and Radiographic Characteristics Between the Satisfied and Dissatisfied Groups

Characteristic	Satisfied ($n = 29$)	Dissatisfied ($n = 15$)	*P* Value
Average age, years, mean ± SD	62.8 ± 8.5	65.6 ± 7.7	0.29
Male sex, *n* (%)	22 (75.9)	8 (53.3)	0.13
Follow-up, months, mean ± SD	21.5 ± 14.5	28.1 ± 13.5	0.15
Preoperative JOA score, mean ± SD	10.7 ± 2.4	11.4 ± 1.7	0.34
Preoperative kyphosis, *n* (%)	3 (10.3)	2 (13.3)	1.00
Type of ossification, *n* (%)			0.13*
Continuous	10 (34.5)	1 (6.7)	
Segmental	5 (17.2)	3 (20.0)	
Mixed	7 (24.1)	3 (20.0)	
Others	7 (24.1)	8 (53.3)	
Hill-shaped ossification, *n* (%)	5 (17.2)	7 (46.7)	0.04
K-line (−), *n* (%)	8 (27.6)	6 (40.0)	0.41
Severe occupying ratio, *n* (%)	4 (13.8)	3 (20.0)	0.85
Presence of IHSI on MRI, *n* (%)	27 (96.4)	12 (80.0)	0.11*
Postoperative kyphosis, *n* (%)	15 (51.7)	11 (73.3)	0.16
Residual ACS on MRI, *n* (%)	7 (25.9)	7 (46.7)	0.17

JOA, Japanese Orthopedic Association; IHSI, intramedullary high signal intensity; MRI, magnetic resonance imaging; ACS, anterior compression of the spinal cord.
*Fisher's exact test.

Table 4. Comparison of the Effectiveness of Surgical Treatment According to Patient-Reported Outcomes Between the Satisfied and Dissatisfied Groups

Parameters	Satisfied ($n = 29$)	Dissatisfied ($n = 15$)	*P* Value
SF-36 PCS (MCID reached)	18 (81.8)	1 (14.3)	<0.01*
NDI (MCID reached)	13 (50.0)	2 (18.2)	0.14*
Neck pain (MCID reached)	6 (21.4)	3 (23.1)	0.91
Arm pain (MCID reached)	11 (37.9)	6 (46.2)	0.62
JOACMEQ (effectiveness)			
CF	12 (46.2)	2 (22.2)	0.26*
UEF	12 (50.0)	3 (30.0)	0.45*
LEF	16 (61.5)	1 (10.0)	<0.01*
BF	9 (33.3)	0 (0.0)	0.09*
QOL	9 (32.1)	1 (7.7)	0.13

SF-36 PCS, Short Form 36 Physical Component Summary; MCID, minimum clinically important difference; NDI, Neck Disability Index; JOACMEQ: Japanese Orthopedic Association Cervical Myelopathy Evaluation Questionnaire; CF, cervical spine function; UEF, upper extremity function; LEF, lower extremity function; BF, bladder function; QOL, quality of life.
*Fisher's exact test.

group had a higher proportion of patients who considered the surgical treatment effective based on the JOACMEQ BF (33.3% vs. 0.0%), but again the difference also did not reach statistical significance ($P = 0.09$).

According to the Jonckheere—Terpstra test, there was no statistically significant association between the duration of follow-up and patient satisfaction rating ($P = 0.15$).

DISCUSSION

Several predictors of poor outcome after laminoplasty in patients with OPLL have been reported.[7-14] Because the concept of laminoplasty through a posterior approach as treatment for patients with OPLL is based on indirect decompression, radiographic parameters related to a larger ossification and cervical kyphotic alignment were considered risk factors for a poor surgical outcome; for instance, physicians could use the K-line as an index to evaluate the cervical alignment and OPLL size at the same time.[11] Fujiyoshi et al[11] reported that patients with a negative K-line demonstrated poorer neurologic improvement compared with those with a positive K-line. Other parameters related to OPLL size and cervical alignment, such as kyphotic cervical alignment, an occupying ratio >60° in the spinal canal, and a hill-shaped ossification also have been identified as predictors of poor surgical outcome of laminoplasty for cervical compressive myelopathy due to OPLL.[6-10] The assessment of the surgical outcome in these reports was based on conventional doctor-reported functional outcomes, such as the JOA score, however.

We used PROs to evaluate HRQOL and pain during the preoperative and postoperative periods. To our knowledge, this is the first report to examine the association between several known prognostic radiographic factors and patient-reported satisfaction after laminoplasty for cervical compressive myelopathy caused by OPLL. Iwasaki et al[13] previously reported that a hill-shaped OPLL was a predictor of a poor outcome following laminoplasty, as evaluated using the JOA recovery rate. The outcome in the present study, showing a smaller proportion of patients with a hill-shaped OPLL in the satisfied group compared with the dissatisfied group, was consistent with that in the previous study. For patients with a hill-shaped OPLL, the indications for laminoplasty should be thoroughly considered, and alternative surgical methods, such as anterior decompression and fusion surgery or posterior decompression surgery with additional fusion, should be considered as well.

We also examined the association between the postoperative radiographic parameters and patient satisfaction. Based on the surgical results of laminoplasty in patients with cervical spondylotic myelopathy, postoperative kyphosis and residual anterior compression of the spinal cord were thought to cause worse outcomes[34,36]; however, few studies have examined the association between postoperative kyphosis and the surgical results of laminoplasty in patients with OPLL.[37,38] In the present study of postoperative satisfaction in patients with OPLL, we found no association between postoperative kyphosis and dissatisfaction. Although our sample size may be too small to support this conclusion, some previous studies of the surgical results of laminoplasty in patients with OPLL have reported similar findings. For example, Iwasaki et al,[37] in a study of the long-term (>10 years) results of laminoplasty in patients with OPLL, reported that postoperative deterioration of cervical alignment to kyphosis did not cause neurologic deterioration.[37] Moreover, Lee et al[38] recently reported that cervical laminoplasty increased the risk of cervical kyphotic change, but that this postoperative radiographic change was not related to clinical outcomes, including JOA, SF-36, neck pain, or NDI scores.[38]

Although sagittal imbalance has been identified as a major source of pain and disability after cervical fusion surgery,[39,40] the negative impact of postoperative kyphosis on the surgical results of laminoplasty for cervical myelopathy due to OPLL remains controversial, despite a common perception that postoperative kyphosis results in a less indirect decompression effect after laminoplasty. One potential explanation for this is that some patterns of ossification fused to the spinal column might affect both the postoperative alignment change and the surgical outcome. Because we were unable to identify potential reasons to explain the relationship between postoperative kyphotic alignment and surgical outcome in this small study, further large-scale analyses designed to investigate the mechanism of clinical outcomes in patients with OPLL and postoperative kyphosis are warranted.

Several reports on patient satisfaction after laminoplasty in patients with cervical compressive myelopathy have been published. Kimura et al[24] reported that postoperative satisfaction after laminoplasty for cervical compressive myelopathy, including spondylosis and OPLL, was associated with some preoperative domains of the SF-36. Using almost the same inclusion criteria, we also previously analyzed the associations between patient satisfaction and several PROs, including the preoperative and postoperative outcomes, and the effectiveness of surgical treatment using the JOACMEQ.[26] We found that patients reporting effective surgical treatment of lower extremity function were satisfied. In a study focused on patients with OPLL, Fujimori et al[23] demonstrated that the JOA score and several postoperative PROs were associated with patient satisfaction. Their stepwise logistic regression analysis revealed that the SF-36 PF, JOACMEQ QOL, JOACMEQ LEF, and maximum recovery rate were correlated with patient satisfaction. The results of these previous studies, indicating that postoperative physical functions, especially in the lower extremities, were associated with satisfaction in patients with OPLL who underwent laminoplasty, support our present findings. One advantage of the present study is that it provides more practical clinical research on the effectiveness of surgical treatment using the concept of the MCID and the definition of the JOACMEQ.

In this study, we used the MCID to evaluate the effectiveness of surgical treatment with regard to HRQOL and pain. The number of studies evaluating the clinical impact of spinal surgery on HRQOL has been increasing, and several PROs have been used to assess the effects of treatments. The most common metrics used to assess the true clinical impact of surgery are the MCID and the substantial clinical benefit (SCB). The MCID is the smallest change in the score necessary for the patients to be able to discern improvement,[15,16] whereas the SCB is a realistic target value indicating the amount of improvement necessary for the patient to feel that he or she is doing much better.[41] It is important to recognize that a statistically significant difference does not necessarily mean a clinically meaningful difference in HRQOL or a pain scale.[42,43] In this study, although the changes in arm pain and the SF-36 PCS were considered statistically significant, a comparison of the preoperative and postoperative values for the overall population in this study showed that only the SF-36 PCS reached the MCID (and also reached 6.5 points as the SCB).[15]

Studies planned to evaluate the impact of surgery on HRQOL and pain should be focused on expressing a clinically important difference resulting from the surgical intervention, not a statistically significant difference. Our present results suggest that patients with OPLL undergoing laminoplasty could perceive a difference in clinical physical function, but could not recognize any difference in arm pain, neck pain, or neck disability status. Moreover, the satisfied group had a higher proportion of patients reaching the MCID on the SF-36 PCS compared with the dissatisfied group, suggesting that patients with OPLL who were able to recognize a difference in clinical physical function after laminoplasty were satisfied with the surgery.

The JOACMEQ, a patient-based method for evaluating cervical compressive myelopathy, consists of 24 questions.[36] Five functional domains, including cervical spine function, upper extremity function, lower extremity function, bladder function, and QOL, are calculated separately according to the formulas provided. Each functional score ranges from 0 to 100, with higher scores indicating a better condition. Therapeutic effectiveness also can be evaluated using this scoring system. The advantage of using this patient-reported scoring system is that physicians can evaluate each function, such as upper extremity, lower extremity, and bladder functions, based on the patient-reported function and HRQOL. Several reports on cervical compressive myelopathy using this scoring system have been published to date.[23,26,44-49] Further research examining the association between the definition of therapeutic effectiveness using this scoring system and the change in values between the preoperative and postoperative periods using the concept of the MCID will be of interest.

Postoperative complications or the need for further surgery may affect patient satisfaction. Although a previous study examining PROs after spinal column osteotomy reported an influence on PROs in requiring a major reoperation,[50] the influence of complications and further surgery on postoperative satisfaction remains unclear. In this study, presumably owing to the relatively short duration of follow-up, no patients required further surgery because of OPLL progression. In addition, only 1 patient underwent further surgery for collapse of the cervical lamina, at 7 months after the index surgery. Because of the small number of adverse events, we were unable to include the cases with postoperative complications or further surgery as potential predictors in our analysis. If the number of patients with postoperative complications increases as the follow-up period progresses, then further studies examining the association between patient satisfaction and postoperative complications may be conducted.

This study has several limitations, starting with the relatively small number of cases. Because the small number of patients did not allow for a multivariate analysis with several variables, we were unable to avoid the impact of important confounding factors among each variable on our results. Thus, our findings, without adjusting for confounding factors, could be merely hypotheses driven by analyses using the data obtained from a small number of patients. Consequently, according to the potential factors identified in this hypothesis-generating study, we plan to conduct further large-scale, multicenter studies in patients with OPLL. Second, there may have been both selection bias and recall bias. Patients with known risk factors for a poor surgical outcome, such as kyphosis or a negative K-line, might have been less likely to be included in this study, because the surgeons may have deemed them contraindicated for laminoplasty. In addition, clinical outcome studies based on PROs have the potential to be affected by recall bias.

Finally, the timing of the follow-up when patient satisfaction and PROs were evaluated varied, ranging from 12 to 89 months. OPLL progression after posterior decompression surgery has been reported to occur with an incidence of 56.5% at 2 years and 71% at 5 years,[51] although we could not evaluate this complication in the present study owing to the lack of postoperative CT images in the same operative period among this cohort. This late-onset postoperative feature in patients with OPLL may have led to a poorer outcome in patients with a longer follow-up. Despite the foregoing limitations, however, we believe that this study provides valuable information that is of clinical importance.

In conclusion, patient satisfaction after laminoplasty for cervical OPLL was insufficient in patients with a hill-shaped ossification. The indications for laminoplasty in patients with a hill-shaped OPLL must be carefully considered, and the procedure should be avoided when appropriate. Moreover, patient satisfaction was related to postoperative clinical improvement in physical function, especially lower extremity function. We believe that our findings provide useful information that can help improve our understanding of the selection of treatment for cervical compressive myelopathy caused by OPLL.

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Effect of Preoperative Sagittal Balance on Cervical Laminoplasty Outcomes

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Study Design. Retrospective case series.
Objective. To clarify how preoperative global sagittal imbalance influences outcomes in patients with cervical compression myelopathy undergoing cervical laminoplasty.
Summary of Background Data. The influence of sagittal balance on outcomes of cervical laminoplasty remains uncertain.
Methods. The authors retrospectively reviewed data of 106 patients who underwent double-door cervical laminoplasty between 2004 and 2011 and investigated the influence of the C7 sagittal vertical axis (SVA) on outcome scores. Primary outcomes used were Japanese Orthopedic Association (JOA) scores, Numerical Rating Scale for neck or arm pain, the Short Form 36 Health Survey (physical and mental component summary scores), and the Neck Disability Index (NDI).
Results. Ninety-two patients with complete data were eligible for inclusion. The preoperative C7 SVA was $\leq$5 cm in 64 patients (69.6%) and $>$ 5 cm in 28 (30.4%). We compared each parameter by the magnitude of spinal sagittal balance (preoperative C7 SVA $>$ 5 cm *vs.* C7 SVA $\leq$ 5 cm) after adjusting for age via the least square mean analysis because the average age was significantly higher in patients with C7 SVA $>$ 5 cm. As for the radiographic parameters, both C2–7 SVA and C7 SVA were larger in patients when the C7 SVA was $>$ 5 cm. Numerical Rating Scale for postoperative arm pain, postoperative JOA scores, and both pre- and postoperative physical component summary and NDI were worse in patients with C7 SVA $>$ 5 cm; however, the JOA score recovery rate and changes in physical component summary and NDI were not significantly different.
Conclusion. Postoperative functional outcome scores were significantly lower in patients with C7 SVA $>$ 5 cm, although the improvement after cervical laminoplasty was not greatly affected. The involvement of global sagittal balance and cervical regional alignment should be considered in evaluating surgical outcomes for patients undergoing cervical laminoplasty.
Key words: alignment, cervical myelopathy, global balance, laminoplasty, outcome, sagittal balance, sagittal vertical axis.
Level of Evidence: 4
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Cervical laminoplasty is an established procedure for the treatment of cervical compression myelopathy, and relatively good long-term surgical results have been reported.[1,2] One of the advantages of this technique is that it can be applied to multisegmental cord compression cases without fusing the vertebral bodies; this is particularly suitable for the elderly who often have multiple segments involved.[3–5] The possible postoperative complications related to this procedure include posterior axial neck and scapular pain,[6,7] decreased range of motion (ROM),[8,9] and postoperative kyphosis.[10,11]

The known causes of poor surgical outcomes after cervical laminoplasty include cervical regional kyphosis [12] and large anterior factors such as ossification of the longitudinal ligament (OPLL),[13] which appears logical given that the concept of this procedure is a posterior shift of the spinal cord.[14] Increased age at surgery is also reported to affect postoperative neurological recovery.[5,15,16] However, only few reports have investigated the influence of global sagittal spinal balance on surgical outcomes. Because sagittal spinal imbalance can influence health-related quality of life (HRQOL),[17,18] it is reasonable to speculate that not only general outcome scores utilized for the evaluation of

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HRQOL such as the Short-Form 36 (SF-36) Health Survey but also disease-specific outcome scores such as the Japanese Orthopedic Association (JOA) score and Neck Disability Index (NDI) can be influenced by the existence of sagittal imbalance itself, regardless of the degree of myelopathy. Furthermore, patients with global sagittal spinal imbalance may be urged to keep their cervical spine in a hyperlordotic alignment to maintain an upright position of the head, which may not be necessary for those with good sagittal spinal balance.[19,20] As cervical alignment tends to change from lordosis to kyphosis after cervical laminoplasty, such patients may have more difficulty in maintaining their HRQOL with a slight kyphotic change of postoperative cervical alignment. In other words, HRQOL in patients with sagittal spinal imbalance may be influenced more by postoperative regional kyphotic change of the cervical spine after cervical laminoplasty. Therefore, it is necessary to consider the influence of preoperative global sagittal imbalance on the impairment of HRQOL before surgery, even if the cervical region does not appear to be impaired.

The purpose of this study was to clarify how preoperative global sagittal imbalance influences outcome scores in patients with cervical myelopathy undergoing cervical laminoplasty.

MATERIALS AND METHODS

The study protocols were approved by the institutional review board of the authors' institution. We retrospectively reviewed 106 patients with cervical compression myelopathy who underwent double-door laminoplasty between 2004 and 2011 and replied to the patient-reported outcomes questionnaires both pre- and postoperatively at our institution. Patients with rheumatoid arthritis, disc herniation, tumor, trauma, severe lumbar spinal canal stenosis, or previous surgery were not included. Fourteen patients were excluded because they did not undergo radiographic examinations of the whole spine.

Radiological parameters included the measurement of Cobb angles between the C2 and C7 vertebrae with cervical lateral radiographs and the C7 slope and C7 sagittal vertical axis (C7 SVA) with whole-spine standing lateral radiographs. C7 SVA was the distance between the C7 plumb line and posterior corner of the sacrum. The materials were sub-analyzed by the magnitude of sagittal imbalance (preoperative C7 SVA > 5 cm vs C7 SVA ≤ 5 cm). The degree of cervical spinal cord compression was evaluated using midsagittal T2-weighted magnetic resonance imaging (MRI), as previously described, by comparing the sagittal diameter of the spinal cord at the maximum compression level with that of C1 and C7 [maximum spinal cord compression (MSCC)].[21] A higher MSCC means that the patient has more severe cervical spinal cord compression.

Primary outcome measures used were JOA scores, Numerical Rating Scale (NRS) for each part of the body, the SF-36 Health Survey [physical and mental component summary scores (PCS and MCS, respectively)], and NDI.

SPSS v18 software (SPSS, Chicago, IL) was used for the Wilcoxon signed rank test, Mann–Whitney *U* test, and Spearman rank correlation coefficient. Least square mean analysis was used to compare each variable by the magnitude of sagittal imbalance (C7 SVA > 5 cm *vs.* C7 SVA ≤ 5 cm) after adjusting for age using the SAS procedure PROC GLM (SAS Institute, Inc., Cary, NC). A *P* value of < 0.05 was considered statistically significant.

RESULTS

Ninety-two patients with complete data were eligible for inclusion. There were 61 males and 31 females with a mean age of 64 years (range, 34–82 yrs), and the mean follow-up period was 27 months (range, 12–60 months) (Table 1). The pre- and postoperative radiographic parameters were not significantly different, except for cervical ROM (Table 2).

The mean preoperative C7 SVA was 3.4 cm (−4.0–20.0 cm), which had a positive correlation with age ($P = 0.36$) (Figure 1). The preoperative C7 SVA was ≤ 5 cm in 64 patients (69.6%) and > 5 cm in 28 (30.4%). C7 SVA worsened and increased to > 5 cm in four of the 64 patients (6.3%) with preoperative C7 SVA ≤ 5 cm, whereas C7 SVA improved and reduced to < 5 cm in two the 27 patients (7.4%) with preoperative C7 SVA > 5 cm. However, the average pre- and postoperative C7 SVA measurements were not significantly different (Table 2) and were strongly correlated ($P = 0.86$).

Then, we compared demographic data and each parameter between the two groups by the magnitude of spinal sagittal balance (preoperative C7 SVA > 5 cm *vs.* C7 SVA ≤ 5 cm; Table 3). As expected, the average age was significantly different between the two groups. Therefore, further comparison was performed after adjusting for age *via* least square mean analysis. As for the radiographic and MRI parameters, there were no statistical differences between the two groups, except for C2–7 SVA and lumbar lordosis (Table 4). NRS scores for postoperative arm pain were significantly higher in patients with C7 SVA > 5 cm. Similarly, the JOA showed worse scores only postoperatively in patients with C7 SVA > 5 cm ($P = 0.01$); however, the preoperative JOA score tended to be lower in those with C7 SVA > 5 cm ($P = 0.06$) and the recovery rates of the JOA scores were not significantly different between the groups. Both pre- and postoperative PCS and NDI were inferior for

TABLE 1. Demographic Data of Patients (N = 92)

Age (yrs)	64 (range, 34–82)
Sex (Males/Females)	61/31
Follow-up period (months)	27 (range, 12–60)
CSM/OPLL	54/38

CSM indicates cervical spondylotic myelopathy; OPLL, ossification of posterior longitudinal ligament.

TABLE 2. Pre- and Postoperative Radiographic Measurements

	Preoperative		Postoperative		
	Average	SD	Average	SD	*P*
C2C7 Cobb (degrees)	9.0	9.5	8.8	12.0	0.83
ROM (degrees)	40.6	15.5	25.4	12.7	0.00
C7 SVA (cm)	3.4	4.5	3.6	4.5	0.23
C7 slope (degrees)	26.0	8.8	25.6	9.4	0.69
C2–7 SVA (cm)	2.5	3.3	2.2	1.5	0.42

ROM indicates range of motion; SD, standard deviation; SVA, sagittal vertical axis.

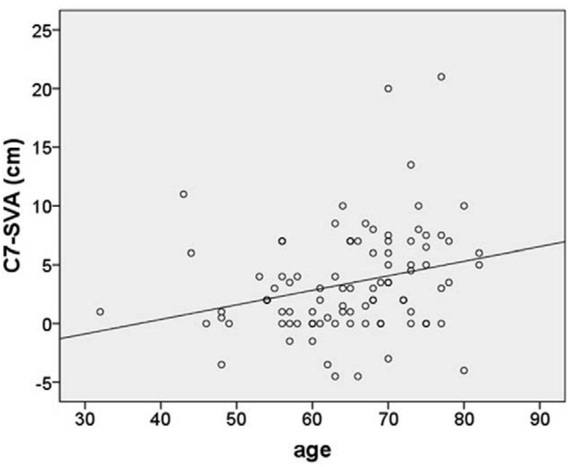

Figure 1. Correlation between age and C7 SVA. C7 SVA was positively correlated with age ($P=0.36$).

patients with C7 SVA > 5 cm. Changes in PCS and NDI were not significantly different.

DISCUSSION

We sought to clarify the influence of global sagittal imbalance on outcome scores in patients with cervical myelopathy who underwent laminoplasty and found that each of our outcomes measurements showed worse scores in patients with C7 SVA > 5 cm. NRS for postoperative arm pain, postoperative JOA scores, and both pre- and postoperative PCS and NDI were worse in patients with C7 SVA > 5 cm; however, the JOA score recovery rate and changes in PCS and NDI were not significantly different. Considering the above results, we speculate that postoperative outcome scores tend to be lower in patients with global sagittal imbalance, although the degree of neurological improvement after cervical laminoplasty may not be greatly affected by the presence of spinal sagittal imbalance. To the best of our knowledge, this is the first study to report an influence of global sagittal balance on HRQOL outcomes in patients undergoing cervical laminoplasty.

There are two possibilities for the worse outcome scores in patients with C7 SVA > 5 cm. The first possibility is the influence of coexisting global sagittal imbalance. It is reasonable to speculate that patients with global sagittal imbalance have worse general HRQOL outcomes such as SF-36 PCS. Many authors have reported the correlation between sagittal imbalance, defined as a C7 plum line of ≥5 cm anterior to the posterior superior sacral margin, and inferior functional outcomes in patients with thoracolumbar disorders.[18,20,22,23] In addition, such patients exhibit walking disability as a result of the sagittal imbalance itself, which can affect the lower extremity motor scores on the JOA. NDI is also influenced by sagittal imbalance because those patients may have difficulty gazing, which affects regional alignment and neck functions. The fact that both pre- and postoperative outcome scores were inferior in patients with C7 SVA > 5 cm indicates possible involvement of sagittal imbalance itself.

One important factor that can affect global sagittal balance is age, which is reported to influence surgical outcomes after cervical laminoplasty.[3–5] In our study, C7 SVA correlated with age. However, we showed that patients with C7 SVA > 5 cm had worse pre- and postoperative functional

TABLE 3. Demographic Data of Patients According to Preoperative C7 SVA

	C7 SVA ≤ 5 cm	C7 SVA > 5 cm	
	N = 65	N = 27	*P*
Age (yrs)	63.4	68.2	0.03
Sex (Males/Feamles)	44/21	17/10	0.81
Follow-up period (months)	27	24	0.38
CSM / OPLL	38/27	16/11	0.94

CSM indicates cervical spondylotic myelopathy; OPLL, ossification of posterior longitudinal ligament; SVA, sagittal vertical axis.

TABLE 4. Outcome Scores and Imaging Parameters According to Preoperative C7SVA After Adjusting for Age

		C7 SVA ≤ 5 cm		C7 SVA > 5 cm		
		N = 65		N = 27		
		Average	SE	Average	SE	*P*
Outcome values						
NRS						
Neck pain	preoperative	3.3	0.4	3.8	0.7	0.57
	postoperative	2.7	0.3	3.5	0.5	0.19
Arm pain	preoperative	4.1	0.4	4.2	0.6	0.91
	postoperative	2.4	0.3	3.8	0.5	0.02
JOA score	preoperative	10.7	0.3	9.6	0.5	0.06
	postoperative	13.9	0.2	12.6	0.4	0.01
	recorery rate	47.8	3.8	43.7	6.5	0.58
NDI	preoperative	32.6	2.3	43.0	3.7	0.02
	postoperative	25.7	1.8	33.5	3.0	0.03
	change	6.9	2.3	7.5	3.7	0.58
PCS	preoperative	25.1	2.3	12.2	3.7	0.00
	postoperative	36.8	2.0	19.8	3.4	<0.001
	change	11.7	2.4	7.6	3.9	0.29
MCS	preoperative	48.2	1.6	49.9	2.5	0.57
	postoperative	49.4	1.3	51.9	2.1	0.32
	change	1.2	1.7	2.0	2.7	0.79
Imaging parameters						
C2C7 Cobb	preoperative	8.8	1.2	9.0	1.9	0.90
(degrees)	postoperative	9.0	1.5	7.2	2.5	0.52
ROM	preoperative	41.9	2.0	34.9	3.5	0.09
(degrees)	postoperative	26.1	1.6	22.0	2.8	0.20
C7 SVA	preoperative	1.3	0.3	8.6	0.6	<0.001
(cm)	postoperative	1.6	0.4	8.6	0.6	<0.001
C7 slope	preoperative	25.3	1.1	28.4	1.8	0.16
(degrees)	postoperative	24.6	1.2	28.7	1.9	0.07
C2–7 SVA	preoperative	2.1	0.4	4.1	0.6	0.01
(cm)	postoperative	2.0	0.2	3.2	0.3	0.01
Thoracic kyphosis	preoperative	35.7	1.4	35.3	2.3	0.90
(degrees)	postoperative	37.4	1.5	35.2	2.6	0.47
Lumbar ordosis	preoperative	45.7	1.3	33.6	2.2	<0.001
(degrees)	postoperative	44.9	1.4	32.3	2.3	<0.001
Sacral slope	preoperative	32.0	0.8	29.5	1.8	0.11
(degrees)	postoperative	32.2	0.8	29.1	1.4	0.06
Pelvic tilt	preoperative	14.7	0.9	17.1	1.5	0.17
(degrees)	postoperative	14.8	1.0	18.3	1.7	0.09
Pelvic incidence	preoperative	46.7	1.3	46.6	2.0	0.96
(degrees)	postoperative	47.0	1.2	47.3	2.1	0.89
MSCC on MRI	preoperative	45.2	2.1	47.9	3.5	0.51

JOA indicates Japanese Orthopedic Association; MCS, mental component summary; MRI, magnetic resonance imaging; MSCC, maximum spinal cord compression; NDI, Neck Disability Index; NRS, Numerical Rating Scale; PCS, physical component summary; ROM, range of motion; SE, standard error; SVA, sagittal vertical axis.

outcomes, even after adjusting for age, which indicates that the relatively low functional outcome scores in patients with C7 SVA > 5 cm mainly resulted from the presence of sagittal imbalance itself and not from age. The relatively poorer surgical outcomes reported in the past for the elderly who have undergone cervical laminoplasty may be partly because of the influence of the global sagittal imbalance of such patients. Nevertheless, we should consider the influence of sagittal balance when treating the elderly with cervical myelopathy.

Another possible reason for the low functional outcome scores in patients with global sagittal imbalance is the influence of regional alignment, particularly of the C2–7 SVA. In this study, the subjects with C7 SVA > 5 cm also had regional sagittal imbalance in their neck. There have been several reports about the influence of C2–7 SVA on cervical myelopathy or surgical results. Tang *et al*[24] reported a relationship between postoperative C2–7 SVA and postoperative NDI and PCS of SF-36 in patients undergoing cervical fusion surgery. Smith *et al*[25] reported that C2–7 SVA correlated with myelopathy severity, as measured by modified JOA scores. Roguski *et al*[26] also investigated the correlation between C2–7 SVA and HRQOL outcome scores in 21 patients with anterior surgery and in 28 patients with posterior surgery for cervical myelopathy. They showed statistical correlation between pre- and postoperative C2–7 SVA and improvement in the PCS; the majority of patients with C2–7 SVA > 40 mm did not improve after surgical intervention. In our cases, C2–7 SVA was significantly larger in patients with C7 SVA > 5 cm, which was surprising to a certain extent because we expected that cervical hyperlordosis would have compensated for the malposition of the head in patients with global sagittal imbalance. It is unclear why such patients did not show hyperlordosis of the neck to keep their head position; however, we speculate that muscle atrophy resulting from cervical myelopathy may have made the compensation impossible. Here, we classified patients into two groups according to the magnitude of C7 SVA because the basic concept of this study was to investigate influence of global sagittal balance on outcome scores. Therefore, multivariable analysis would be necessary to evaluate the true impact of global sagittal balance and regional cervical alignment on cervical laminoplasty outcomes by setting one outcome as a dependent variable. Nevertheless, we believe that both global sagittal imbalance and regional sagittal imbalance affected the functional outcomes scores in our case. Cervical fusion surgery with correction of cervical alignment instead of cervical laminoplasty may lead to better surgical outcomes in such patients, although the patients in this study did show improvements after cervical laminoplasty to some extent.

Postoperative kyphosis of the cervical spine has been reported as a possible adverse event after cervical laminoplasty.[10,11] It is reasonable to speculate that patients with global sagittal imbalance would have more difficulty gazing if such regional kyphosis occurs after laminoplasty. Fortunately, we did not note any severe kyphotic changes of the cervical spine in our cases. Techniques such as laminoplasty or fusion surgery can preserve posterior structure and should be considered in patients with severe global sagittal imbalance.

There were several limitations in this study. First, this is not a comparative study and we could not compare laminoplasty with other procedures such as anterior or posterior fusion surgery. Second, although we classified patients according to the preoperative C7 SVA, some patients showed improvement or deterioration in their sagittal balance postoperatively. However, because the number of such patients was not so large and the pre- and postoperative C7 SVA was well correlated, we believe that the results were not greatly affected by the postoperative changes in sagittal balance. Third, we did not include cases with severe sagittal imbalance. Treatment for the deformity should be paramount when treating such patients. Finally, the small number of patients made multivariable analysis of the imaging parameters impossible. A prospective study with a larger number of patients will elucidate these problems.

In conclusion, in patients undergoing cervical laminoplasty for cervical myelopathy, postoperative functional outcome scores appear to be lower in those with C7 SVA > 5 cm, although the improvement after cervical laminoplasty is not greatly affected. The involvement of global sagittal balance and cervical regional alignment should be considered when evaluating surgical outcomes for cervical laminoplasty, particularly for the elderly.

➢ Key Points

- ❑ We investigated the influence of global sagittal balance on outcomes of 92 patients undergoing cervical laminoplasty.
- ❑ Postoperative functional outcome scores were significantly lower in patients with C7 SVA > 5 cm, although the improvement after cervical laminoplasty was not greatly affected.
- ❑ The involvement of global sagittal balance and cervical regional alignment should be considered in evaluating surgical outcomes for patients undergoing cervical laminoplasty.

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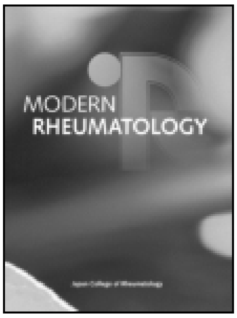

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ORIGINAL ARTICLE

The impact of joint disease on the Modified Health Assessment Questionnaire scores in rheumatoid arthritis patients: A cross-sectional study using the National Database of Rheumatic Diseases by iR-net in Japan

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Abstract

Objectives: To investigate the effect of bilateral and unilateral joint disease on the Modified Health Assessment Questionnaire (MHAQ) scores and the differences in joint weighting in rheumatoid arthritis patients.

Methods: A total of 9212 subjects from the Japanese nationwide cohort database NinJa, 2011, were analyzed. The presence or absence of disease in each joint, including swelling and/or tenderness, was investigated. The correlations between bilateral and unilateral disease in each joint and MHAQ scores were investigated using multivariable logistic regression analysis.

Results: The patients' mean age and disease duration was 63.2 and 12.2 years, respectively. The Disease Activity Score-28 was 3.3. The odds ratios of physical impairment according to the MHAQ using multivariable logistic regression models for bilateral and unilateral joints, respectively, were: shoulder, 4.0 and 1.8; elbow, 2.6 and 1.8; wrist, 1.9 and 1.5; hip, 1.7 and 3.0; knee, 2.6 and 1.9; ankle, 2.3 and 2.0, finger, 1.4 and 1.2; and toe, 1.0 and 1.1. The shoulder, elbow, wrist, knee, and ankle had a significant effect on physical impairment.

Conclusions: The MHAQ score was significantly affected by shoulder, elbow, wrist, knee, and ankle joint disease. Furthermore, bilateral disease tended to have a greater effect on physical impairment than unilateral disease.

Keywords

Cohort study, Joint involvement, Physical function, Rheumatoid arthritis, Scoring system

History

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Introduction

Rheumatoid arthritis (RA) is a chronic inflammatory disease caused by activation of the osteoclast pathway, resulting in local bone destruction around joints and systemic osteoporosis. In addition, reduction of the joint range of motion and the destruction of joints lead to reduced daily physical activity [1]. With the development of pharmacotherapies, it has become possible to control the disease activity of RA and avoid worsening of physical function and activity. One of the major goals of RA treatment is to avoid disability. The Disease Activity Score (DAS) 28 is widely used for the assessment in RA mainly focusing on joint inflammation, and consists of swollen joint counts, erythrocyte sedimentation rate (ESR), and patient's global assessment [2]. The DAS28 mainly focuses on the upper extremities, and evaluates joints including the shoulder, elbow, wrist, finger, and knee. On the other hand, the Health Assessment Questionnaire (HAQ) measures functional disability [3]. Its modified version, the modified HAQ (MHAQ), was developed to assess patients' functional capacity in daily activities, such as dressing and grooming, standing up, eating, walking, hygiene, reach, grip, and common daily activities, in clinical trials and daily practice [4].

Previous studies showed that the HAQ score was associated with disease activity, swollen and tender joints, and laboratory data [5,6]. Accounting of joint diseases is important to evaluate the physical function of RA patients. On the other hand, a few studies showed that the impact of the impaired joint on the functional disability differed among individual joints [7]. However, no previous study has examined how joint disease affects physical function when the disorder is bilateral or unilateral. In addition, a consensus has not been reached for determining an appropriate weighted score system for joint evaluation in RA patients.

Using the National Database of Rheumatic Diseases by iR-net in Japan (NinJa), a multicenter, rheumatic disease database, the present study investigated the effect of bilateral and unilateral joint disease in the shoulder, elbow, wrist, hip, knee, ankle, finger, and toe on the MHAQ scores and the differences in joint weighting in RA patients.

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Materials and methods

Data source

The study protocol was reviewed and approved by the Research Ethics Committees of the National Hospital Organization and each participating hospital, and all patients enrolled provided written informed consent. NinJa is a nationwide, multicenter, observational cohort database of rheumatic diseases that was established in 2002 in Japan [8]. The collected data consist of two components: one is the patient information over the course of the year (outcome, death, hospitalization, operation, number of total joint arthroplasties in large joints [hip, knee, shoulder, and elbow], malignancy, and tuberculosis), and the other is the information collected on an arbitrary day in the daily clinical practice (tender-joint and swollen-joint count, MHAQ Steinbrocker functional classification, Steinbrocker stage, patient global and pain visual analog scales [VAS], doctor VAS, ESR, C-reactive protein [CRP], DAS28-ESR, DAS28-CRP, and use of corticosteroids, methotrexate, and nonsteroidal anti-inflammatory drugs).

Patients

The subjects were the 9212 patients (1766 men, 7446 women) with complete medical records among the 10,367 patients registered in NinJa in fiscal year 2011 (from April 2011 to March 2012). The presence or absence of disease in each joint (swelling and/or tenderness were considered as disease) and whether the disease was bilateral or unilateral were investigated. The presence of disease in the finger or toe joints was defined as swelling and/or tenderness in at least one metacarpophalangeal joint, metatarsophalangeal joint, or proximal interphalangeal joint. In addition, if a joint had been treated with a surgical procedure, it was defined as having absence of disease.

Statistical analyses

Descriptive statistics were used to analyze the clinical information, demographic factors, and other test data. Continuous variables were expressed as means and standard deviation (SD). Furthermore, the correlation between the MHAQ and DAS28-ESR scores were examined by Spearman correlation coefficient.

The MHAQ median score of this study was 0.25. Functional impairment was defined as a MHAQ score ≥ 0.25. The MHAQ score of the functional impairment group was evaluated using univariate logistic regression, and the odds ratio was calculated. In the next step, the variables with a p value of <0.2 in the univariate analyses were included in a stepwise multivariable logistic regression model for functional impairment.

Receiver operating characteristic (ROC) curve analysis was performed to develop a support tool of functional impairment. Discriminatory power is the ability to identify which patients are likely to have a functional impairment, and it was determined using ROC curve analysis, in which an area under the ROC curve (AUC) of 1.0 indicated perfect discrimination, and an AUC ≥ 0.7 was, in general, considered to indicate acceptable discrimination [9]. Finally, to examine the performance of the support tool, we calculated the sensitivity and specificity. Statistical analyses were conducted using the JMP 10.0.2 software program (SAS, Cary, NC). All statistical tests were 2-tailed, and a significance level of 0.05 was used.

Results

The clinical features of the 9212 patients with RA are shown in Table 1. The patients had a mean ± SD age and disease duration of 63.2 ± 12.9 years and 12.2 ± 10.7 years, respectively. The majority of subjects had moderate disease activity (mean DAS28-ESR score, 3.3 ± 1.3). The mean MHAQ score was 0.48 ± 0.64.

Table 1. Baseline demographic and clinical characteristics of 9212 patients with rheumatoid arthritis.

Age, years	63.2 ± 12.9
Female, %	80.1
RA disease duration, years	12.2 ± 10.7
C-reactive protein, mg/100 mL	0.7 ± 1.3
Erythrocyte sedimentation rate, mm/h	30.3 ± 25.7
Patient's pain VAS, mm	27.1 ± 23.9
Patient's general VAS, mm	27.9 ± 23.9
Physician's general VAS, mm	17.9 ± 16.6
DAS28-ESR score	3.3 ± 1.3
DAS28-CRP score	2.6 ± 1.1
MTX use, %	61.6
MTX dosage, mg/week	5.2 ± 4.7
Corticosteroid use, %	46.7
Corticosteroid dosage, mg/day	4.2 ± 2.7
MHAQ score	0.48 ± 0.64
MHAQ score, median	0.25

Values are mean ± standard deviation unless otherwise indicated.
CRP, C-reactive protein; DAS, Disease Activity Score; ESR, erythrocyte sedimentation rate; MHAQ, Modified Health Assessment Questionnaire; MTX, methotrexate; RA, rheumatoid arthritis; VAS, visual analog scale.

The two most frequently affected joints were the finger joints (42.2%) and wrist (36.6%), followed by the knee (21.2%), ankle (20.9%), toe joints (18.7%), elbow (17.8%), and shoulder (11.5%). In contrast, the frequency of hip joint involvement was small (2.0%) (Figure 1).

There was a moderate correlation between the MHAQ and DAS28 scores by Spearman correlation coefficient ($r = 0.52$, $p < 0.01$). Significant associations were observed between the MHAQ scores and bilateral and unilateral disease of all joints except for bilateral disease of the hip and bilateral and unilateral disease of the toes. The odds ratios [95% confidence intervals] using multivariable logistic regression models for bilateral and unilateral joint, respectively, were as follows: shoulder, 4.0 [2.9–5.6] and 1.8 [1.5–2.1]; elbow, 2.6 [2.1–3.4] and 1.8 [1.5–2.1]; wrist, 1.9 [1.7–2.2] and 1.5 [1.3–1.7]; hip, 1.7 [0.7–4.7] and 3.0 [2.0–4.7]; knee, 2.6 [2.2–3.2] and 1.9 [1.7–2.2]; ankle, 2.3 [1.9–3.0] and 2.0 [1.8–2.4]; finger, 1.4 [1.2–1.5] and 1.2 [1.0–1.3]; and toe, 1.0 [0.8–1.3] and 1.1 [0.9–1.3] (Figure 2).

To develop a weighted scoring system from the results of this analysis, an integer score derived from the β-coefficient was assigned to each identified factor [10]. In this study, for each patient, all applicable score values were summed up to attain a total score. Regarding the odds ratio, an integer score was assigned to each identified bilateral and unilateral joint disease, respectively, as follows: shoulder, 4 points and 2 points; elbow, 3 points and 2 points; wrist, 2 points and 2 points; hip, 0 points and 3 points; knee, 3 points and 2 points; ankle 2 points and 2 points; and finger, 1 point and 1 point (Table 2). The total scores for each patient ranged from 0 to 18. The mean ± SD of the total scores was 2.5 ± 2.8. The results of ROC analysis were as follows: cut-off value, 3 points; AUC, 0.709; sensitivity, 58.6%; and specificity, 72.8% (Figure 3). We divided the patients into two groups by using a weighted scoring system cut-off value of 3 points. The distribution of patients and the mean MHAQ score of each group based on a weighted scoring system cut-off value of 3 points are shown in Table 3.

Discussion

In our study, the effects of disease of various joints on physical function were examined, and the findings showed that joint disease of the shoulders, elbows, knees, and ankles had a

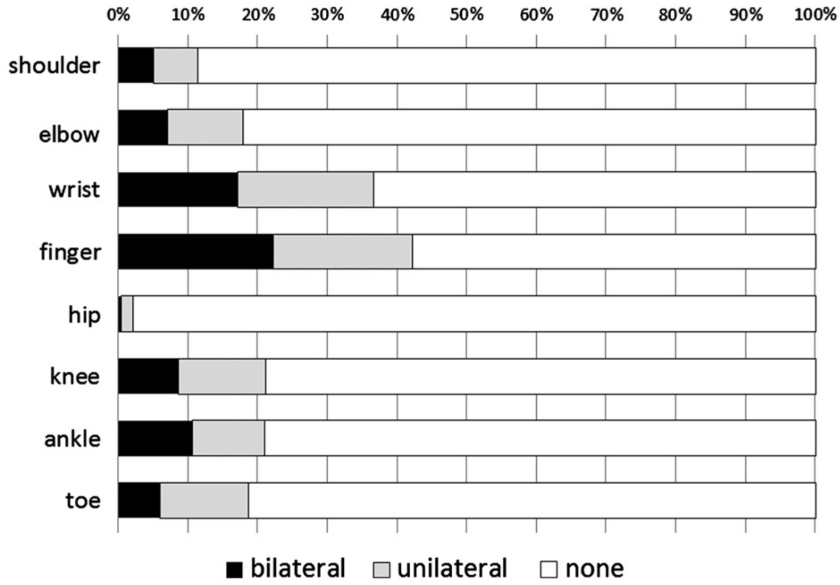

Figure 1. Percentage of involvement of each joint in rheumatoid arthritis patients. Black bars indicate bilaterally affected joints. Gray bars indicate unilaterally affected joints.

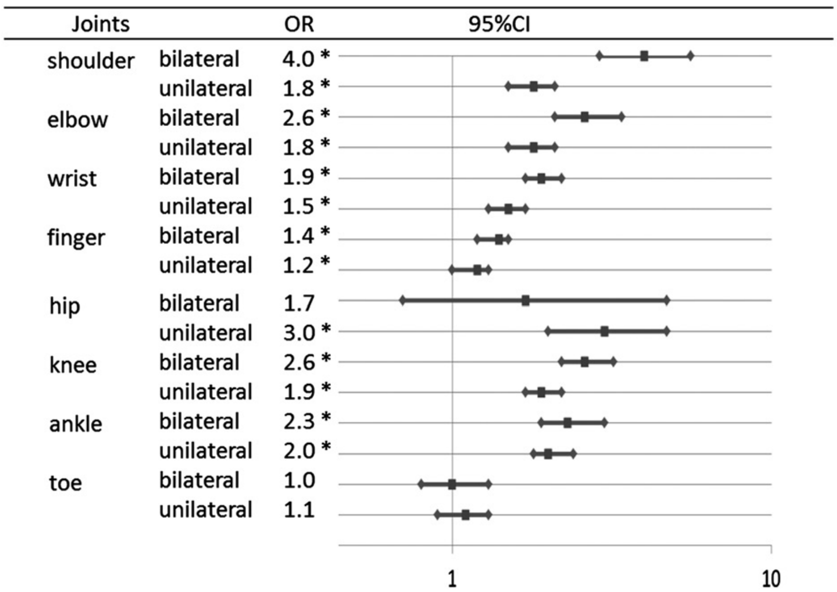

Figure 2. The odds ratios (ORs) and 95% confidence intervals (CIs) of physical impairment using multivariable logistic regression models for each joint with bilateral and unilateral disease. $*p<0.05$.

significant effect on physical function. The findings also showed that deterioration of physical function was more severe when the disease affected the joints bilaterally than when the disease was unilateral. In addition, a clinically useful scoring system was developed based on these findings, allowing for weighting the scores, depending on whether each joint was bilaterally or unilaterally affected.

Thus far, a number of studies have shown that disease activity and physical function are correlated in RA [11–13]. In addition, painful and swollen joints can particularly lead to deterioration of physical function, regardless of disease duration [5,14,15].

Physical function assessments of joints in RA patients have previously been conducted on 68 joints [16] and 28 joints [2,17], and all joints were scored in exactly the same manner. However, the percentages of morbidity were different for every joint. In our study, the morbidity rates were high in the following joints in descending order: finger, wrist, and knee joints; our findings were consistent with those of previous reports [18,19]. Thus, the morbidity rate was different in each joint type, and the impact on physical function may be different depending on the affected joint. Reports from cross-sectional studies have mentioned that the type of joint such as the shoulder, knee, elbow, wrist, or ankle had a

Table 2. Multivariable predictors of physical impairment according to the MHAQ score and joint scoring system as a support tool.

Characteristic	Regression β-coefficient	95% CI	Score*
Shoulder bilateral	4.0	2.9–5.6	4
Shoulder unilateral	1.8	1.5–2.1	2
Elbow bilateral	2.6	2.1–3.4	3
Elbow unilateral	1.8	1.5–2.1	2
Wrist bilateral	1.9	1.7–2.2	2
Wrist unilateral	1.5	1.3–1.7	2
Hip unilateral	3.0	2.0–4.7	3
Knee bilateral	2.6	2.2–3.2	3
Knee unilateral	1.9	1.7–2.2	2
Ankle bilateral	2.3	1.9–3.0	2
Ankle unilateral	2.0	1.8–2.4	2
Finger bilateral	1.4	1.2–1.5	1
Finger unilateral	1.2	1.0–1.3	1

*The score was obtained by rounding the raw score to one decimal place if the coefficient was statistically significant.

CI, confidence interval; MHAQ, Modified Health Assessment Questionnaire.

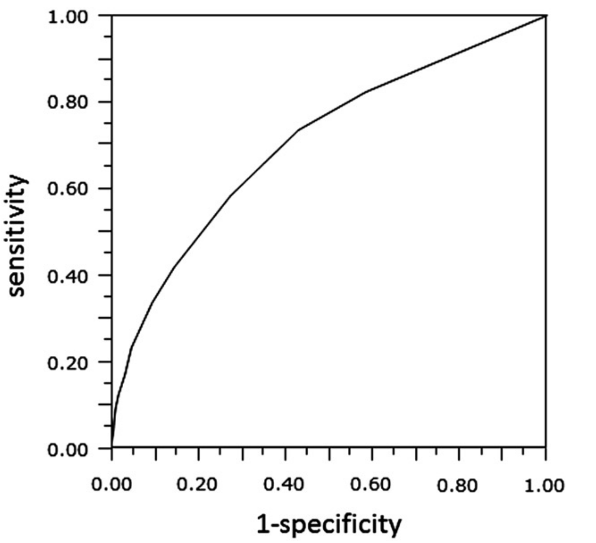

Figure 3. Receiver operating characteristic (ROC) curve for the weighted scoring system. Cut-off value, 3 points; area under the ROC curve, 0.709; sensitivity, 58.6%; specificity, 72.8%.

Table 3. Distribution of patients and the mean MHAQ score of each group based on a weighted scoring system cut-off value of 3 points.

	Score of the weighted scoring system	
	0–2	3–18
Number of patients	5247	3965
%	57.0	43.0
MHAQ score, mean ± SD	0.32 ± 0.53	0.70 ± 0.70
MHAQ score, 95% CI	0.30–0.33	0.68–0.73

CI, confidence interval; MHAQ, Modified Health Assessment Questionnaire; SD, standard deviation.

significant effect on the HAQ score [18]. In addition, a longitudinal study conducted on the same cohort showed that the group, which showed aggravation of the HAQ score during a 3-year period, was significantly affected by diseases of the shoulder, wrist, knee, and ankle joints [19]. A previous study showed that the HAQ score was not affected by joint damage due to radiography, but was affected by pain and range-of-motion limitations of the knee, shoulder, and wrist joints [20].

Our study showed that the MHAQ score was significantly affected by large joints (shoulder, elbow, knee, and ankle, but not the hip) as well as wrist joints, and this was consistent with previous findings [18]. In addition, the effect of ankle joint disease on physical function should also be considered in the daily practice; however, ankle joints are not assessed in the DAS28-ESR. On the other hand, one of the reasons why the presence of bilateral hip joint disease did not significantly affect the MHAQ score could have been the low number of subjects with bilateral hip disease.

The present study showed that in all joints, physical function impairment was more severe when the joints were affected bilaterally than when they were affected unilaterally. No previous report has examined the differences in the effect of bilateral or unilateral joint disease, according to individually affected joints, on physical function. The effect of bilateral and unilateral disorders on physical function tended to be different between upper limb joints and lower limb joints. The difference in the odds ratio of physical impairment between bilateral and unilateral disease was relatively greater in upper limb joints than in lower limb joints; when an upper limb joint is affected unilaterally, the function can be compensated by using the contralateral side.

Applying the weighted scoring system described in this study will account for disease in several joints in RA patients; in those with a cut-off score of 3 or higher, a greater impact of the joint disease on functional disability was predicted. When shoulders, elbows, and knee joints are affected bilaterally, aggressive treatment might be preferable. In addition, using the weighted scoring system may allow for predicting the MHAQ score on the basis of the sites and number of diseased joints. We divided the patients into two groups by using the cut-off value of the weighted scoring system, and the difference in the mean MHAQ score between the two groups was 0.3.

Because physical function and disease activity are correlated [11–13], using the appropriate medication and inhibiting the disease activity are of primary importance in order to maintain physical function. In addition, using the scoring system described in this study to elucidate the joints that are most deeply involved with physical functions may facilitate prioritizing the treatment of diseased joints. This will allow for confirmation of the presence of functional impairments in carrying out activities of daily living and improvement in the inhibition of systemic inflammation through pharmacological treatment, recommendation of self-help devices, rehabilitation therapy, and surgical treatments such as arthrodesis and prosthetic joint replacement surgery, and these measures could reduce the load on joints, and prevent the exacerbation of symptoms and functional impairments.

This study has some limitations. First, this was a cross-sectional study using a cohort database. Second, we did not classify joint disease by tenderness and swelling. We needed to binarize joint disease for the multivariate analysis. Third, we did not evaluate the number affected fingers and toes because we considered that the additional 20 joints might cause confusion in the results of the multivariate analysis. This may have caused unclear differences between the effects of other major joints on the MHAQ; therefore, we evaluated all fingers and toes as a single unit. These two limitations may have affected our scoring system. Fourth, the validation of our scoring system was conducted on a single population; hence, validation of the evidence on another population group will be needed in the future. However, this study also had certain advantages. A large database, in which the MHAQ and DAS28-ESR scores were moderately correlated, was used, and it did not deviate from the general knowledge of the RA population.

Our scoring system has the advantage of providing a cut-off value of 3 points. For examples, according to this weighted scoring system, a patient with bilateral tenderness on the shoulders (4 points) might have worse MHAQ scores than another patient with unilateral tenderness on the knee (2 points). By using this scoring system, we believe that rheumatologists can predict functional disability in a simpler way by examining each joint. Moreover, the scoring system developed in this study will be validated if its use leads to a more accurate prediction of functional disability.

While the MHAQ scores were significantly affected by disease in almost all joints, a greater effect was exerted by the following major joints, in increasing order: ankle, knee, elbow, and shoulder. Bilateral disease tended to have a greater effect on physical impairment than unilateral disease in these major joints and the wrist. We believe that the use of weighted scoring system in the clinical setting will improve the accuracy of predicting functional disability in RA patients.

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Conflict of interest

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RESEARCH ARTICLE

Classification of High Intensity Zones of the Lumbar Spine and Their Association with Other Spinal MRI Phenotypes: The Wakayama Spine Study

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Data Availability Statement: The present study used resident data from two communities in Wakayama prefecture. It is impossible for us to provide and upload these data in a public repository because we have confirmed with these municipalities and residents that data will remain confidential. We will provide anonymized data on request after discussing the contents with the municipalities, as long as researchers are qualified to request these data. Data requests can be made

Abstract

Introduction

High intensity zones (HIZ) of the lumbar spine are a phenotype of the intervertebral disc noted on MRI whose clinical relevance has been debated. Traditionally, T2-weighted (T2W) magnetic resonance imaging (MRI) has been utilized to identify HIZ of lumbar discs. However, controversy exists with regards to HIZ morphology, topography, and association with other MRI spinal phenotypes. Moreover, classification of HIZ has not been thoroughly defined in the past and the use of additional imaging parameters (e.g. T1W MRI) to assist in defining this phenotype has not been addressed.

Materials and Methods

A cross-sectional study of 814 (69.8% females) subjects with mean age of 63.6 years from a homogenous Japanese population was performed. T2W and T1W sagittal 1.5T MRI was obtained on all subjects to assess HIZ from L1-S1. We created a morphological and topographical HIZ classification based on disc level, shape type (round, fissure, vertical, rim, and enlarged), location within the disc (posterior, anterior), and signal type on T1W MRI (low, high and iso intensity) in comparison to the typical high intensity on T2W MRI.

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Abbreviations: HIZ, high intensity zone; DD, disc degeneration; MRI, magnetic resonance imaging; ROAD, Research on Osteoarthritis/Osteoporosis Against Disability.

Results

HIZ was noted in 38.0% of subjects. Of these, the prevalence of posterior, anterior, and both posterior/anterior HIZ in the overall lumbar spine were 47.3%, 42.4%, and 10.4%, respectively. Posterior HIZ was most common, occurring at L4/5 (32.5%) and L5/S1 (47.0%), whereas anterior HIZ was most common at L3/4 (41.8%). T1W iso-intensity type of HIZ was most prevalent (71.8%), followed by T1W high-intensity (21.4%) and T1W low-intensity (6.8%). Of all discs, round types were most prevalent (anterior: 3.6%, posterior: 3.7%) followed by vertical type (posterior: 1.6%). At all affected levels, there was a significant association between HIZ and disc degeneration, disc bulge/protrusion and Modic type II ($p<0.01$). Posterior HIZ and T1W high-intensity type of HIZ were significantly associated with disc bulge/protrusion and disc degeneration ($p<0.01$). In addition, posterior HIZ was significantly associated with Modic type II and III. T1W low-intensity type of HIZ was significantly associated with Modic type II.

Conclusions

This is the first large-scale study reporting a novel classification scheme of HIZ of the lumbar spine. This study is the first that has utilized T2W and T1W MRIs in differentiating HIZ sub-phenotypes. Specific HIZ sub-phenotypes were found to be more associated with specific MRI degenerative changes. With a more detailed description of the HIZ phenotype, this scheme can be standardized for future clinical and research initiatives.

Introduction

Since the advent of magnetic resonance imaging (MRI), there has been a tremendous interest to identify unique spinal phenotypes (e.g. patterns of intervertebral disc degeneration (DD), Modic changes, endplate abnormalities) that may be representative of the degenerative disc process and that may provide insight into determining the painful disc level(s) [1–7]. High-intensity zones (HIZ) of the lumbar spine are an example of a disc phenotype that have gathered widespread interest since their initial report in 1992 by Aprill and Bogduk [8]. Based on their report, HIZ was described as a hyperintense signal in the posterior annulus fibrosus of the disc on T2-weighted (T2W) MRI using only a relatively low-strength 0.6 Tesla scanner in patients with low back pain (LBP) undergoing discography. Since then, numerous reports have surfaced attempting to address the clinical relevance of HIZ and its relationship with LBP, but the significance of this association remains under heated debate [8–16]. Some studies have suggested that lumbar HIZ is related to a concordant pain response on discography and have concluded it to be a significant MRI biomarker for the diagnosis of LBP [8–11]. Alternatively, others studies have not found any association between HIZ with LBP [12–16]. To further complicate this issue, the prevalence of HIZ in symptomatic and asymptomatic populations has varied greatly between reported studies [8–16]. Besides symptomatology, additional controversies exist with regards to its pathology, natural history, and morphology/topography [1, 8–16]. This may be attributed to the lack of a strict phenotype definition of HIZ, proper sampling of the study samples with appropriate demographics, standardized imaging assessment methods, insufficient statistical analyses and consideration of occupational/lifestyle factors, limited knowledge regarding its relationship with other spinal phenotypes, and the poor imaging resolution of particular MRI sequences [1, 8–16].

Understanding the pathogenesis of HIZ is necessary to clearly define its clinical significance with regards to LBP. Previous reports suggested that HIZ was an effect of annular tears leading to an accumulation of disc material that is toxic to the disc and surrounding neural structures, and may cause further degenerative changes within the intervertebral disc [9, 10, 13, 17, 18]. Alternatively, annular tears were also reported to appear in the early stages of DD [19]. Therefore, the relationship between HIZ and DD remains unclear. Traditionally, annular tears require discography, an invasive examination, in order to determine the type of tear that produces degenerative changes and pain. The MRI is a non-invasive method used to characterize HIZ but there is currently no standardized classification system for researchers to phenotype HIZ and most descriptions are based solely upon T2W MRI. As such, these concerns need to be addressed since they are an important initial step to better understand the pathobiology, prevalence, etiology, and clinical significance of HIZ. In addition to the lack of standardized phenotyping, the role of varying morphological/topographical traits of HIZ remains unknown and demand attention.

Coupling of T2W and T1W MRI sequences have been found useful to elaborate upon various spinal phenotypes, such as Modic changes and their classification, and have shed light upon their clinical relevance and decision-making [1, 20–27]. However, to date, no such approach has been adopted for HIZ. Therefore, utilizing a multimodal MRI approach to better characterize the HIZ phenotype is imperative to assist communication between study centers and aid large scale cross-cohort and cross-ethnic analyses. Furthermore, better understanding of HIZ may contribute to more sensitive identification of symptomatic disc levels, prediction and progression of disc or adjacent endplate changes, and potential use for patient selection for regenerative therapies for the disc. It also has potential to be a marker for identifying patients at risk for adjacent segment degeneration/disease in relation to a fusion or arthroplasty procedure.

Due to the limitations as addressed, better classification and understanding of HIZ is needed. Thus, this current study's objectives are three-fold and are based on a large-scale, population-based study. Firstly, we aimed to address the prevalence and morphological/topographical variations of HIZ throughout the lumbar spine using both T2W and T1W MRI. This imaging mapping further facilitated the creation of a novel classification of HIZ. Secondly, we aimed to assess the association of HIZ with other MRI spinal phenotypes.

Methods

Participants

This was a cross-sectional study based on the *Wakayama Spine Study* [28–34], a large population-based study created to address the etiology of common spinal disorders in Japan. Our study population was a sub-cohort of the large-scale population-based cohort study called *Research on Osteoarthritis/Osteoporosis Against Disability* (ROAD). The ROAD study was a nationwide, prospective study of bone and joint diseases consisting of population-based cohorts established in three communities in Japan [35–38]. The participants of ROAD study were recruited from listings of resident registrations in three communities that have different characteristics based on three geographical regions: an urban region in "I town" (Tokyo); a mountainous region in "H town" (Wakayama); and a coastal region in "T town" (Wakayama). *The Wakayama Spine Study* started in mountainous region H town and coastal region T town in Wakayama from 2008 as a population-based cohort [28–34]. For the current study, recruited subjects were 20 years of age or older, irrespective of gender residing in T town who were willing to respond to a survey distributed in 2013.

The inclusion criteria were the ability to walk to the survey site, report data, and sign an informed consent form. Subjects with spinal tumors, infections, chronic inflammatory conditions, previous posterior spinal fusion operation, contraindicated to MRI (e.g., pacemakers) and/or other disqualifiers (e.g., pregnant) were excluded. In total, 857 individuals underwent MRI of the lumbar spine. However, 43 MRI results were not available due to incomplete T1W and T2W sagittal lumbar spine MRI or of quality too poor to read for HIZ. The *Wakayama Spine Study* obtained approval from the local ethics committee of the University of Tokyo, the Tokyo Metropolitan Institute of Gerontology, and Wakayama Medical University. All participants provided their own written informed consent.

MRI Assessment

Lumbar MRI were performed using a mobile MRI unit (Achieva 1.5 T; Philips Medical Systems, Best, The Netherlands) for all participants. On the same day of imaging assessment, participants also completed standardized questionnaires and underwent anthropometric examination, which accounted for height (meters) and weight (kilograms) as well as additional subject demographics (e.g. age [years], sex-type). All participants underwent MRI in the supine position. The imaging protocol included sagittal T2W fast-spin echo (FSE), with a repetition time (TR) of 3000 ms/echo and an echo time (TE) of 120 ms. The field of view (FOV) was 270×270 mm. The sagittal T1W FSE was with a TR of 540 ms/echo, a TE of 10 ms and a FOV of 270×270 mm. All cuts were 5mm thick and 11 total slices were available.

Evaluation of MRI

HIZ was defined as a bright white signal located in the substance of the annulus fibrosus, clearly dissociated from the signal of the nucleus pulposus, which was surrounded by a low-intensity (black) signal of the annulus fibrosus and in turn was appreciably brighter than the cerebrospinal fluid signal at the same level on T2W sagittal MR images of L1-S1 [8, 13]. Our novel classification of HIZ was created based on the disc level, shape (round type, fissure type, vertical type, rim type, and enlarge type), and location within disc (posterior or anterior) (Table 1, Fig 1). We also included details regarding the signal type on either T1W MRI (low-intensity, high-intensity, and iso-intensity signal) and T2W MRI (high-intensity signal) (Table 1, Fig 2). The novel classification scheme was developed based on empirical evidence and observational variants as noted between both imaging modalities in the context of HIZ, further agreed to by a panel of experts on spinal phenotyping.

Sagittal T2W and T1W MRI were used to assess the intervertebral space from L1/L2 to L5/S1. HIZ assessment was performed by a board certified orthopedic surgeon (MT) who was blinded to the background of the subjects. For evaluating intra-observer variability, 20 randomly selected lumbar MRIs were rescored by the same observer (MT) more than 1 month after the first reading, again blinded to the patient details. For inter-observer variability, another 20 MRIs (100 discs) were scored by 2 board certified orthopedic surgeons (MT and HI) using the same classification system. The intra- and inter-observer reliabilities for HIZ on T2W MRI were evaluated by kappa analysis and were 0.92 and 0.84 ($p<0.0001$, 95% confidence interval (CI): 0.96–1.06), respectively. As for the intensity of HIZ on T1W-MRI, kappa analysis of the intra- and inter-observer reliabilities were 0.90 and 0.82 ($p <0.0001$, 95% CI: 0.83–0.95). Kappa statistics >0.90 were considered excellent, 0.80–0.90 were considered good, 0.60–0.80 were considered fair, and <0.60 were considered poor [39, 40]. Any disagreements

Table 1. Assessment of lumbar High Intensity Zones on MRI.

Variables	Definition
Shape	
Round	Concentric or oval cavity
Fissure	Parallel and transverse layer to the adjacent endplate
Vertical	Vertical layer to the adjacent endplate
Rim	Oblique radiating layer from the adajacent endplate
Enlarged	Greater concentric area than typical round HIZ
Horizontal location within disc	
Posterior	HIZ located in the posterior annulus fibrosus
Anteriror	HIZ located in the anterior annulus fibrosus
Signal type on T1W and T2W HIZ image	
T1W low-intensity type of HIZ	Decreased signal than the bone marrow on T1W sagittal MRI
T1W high-intensity type of HIZ	Increased signal than the bone marrow on T1W sagittal MRI
T1W iso-intensity type of HIZ	Same signal than the bone marrow on T1W sagittal MRI

HIZ: high intensity zones, MRI: magnetic resonance imaging, T1W: T1-weighted, T2W: T2-weighted, MRI: magnetic resonance imaging

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in classification were settled by consensus after the reliability assessments were completed. The final classification of HIZ was agreed upon by both observers and DS.

Other spinal MRI phenotypes, such as DD, disc displacement, Modic changes, and Schmorl's node (SN) were also assessed by two board certified orthopedic surgeons (MT and

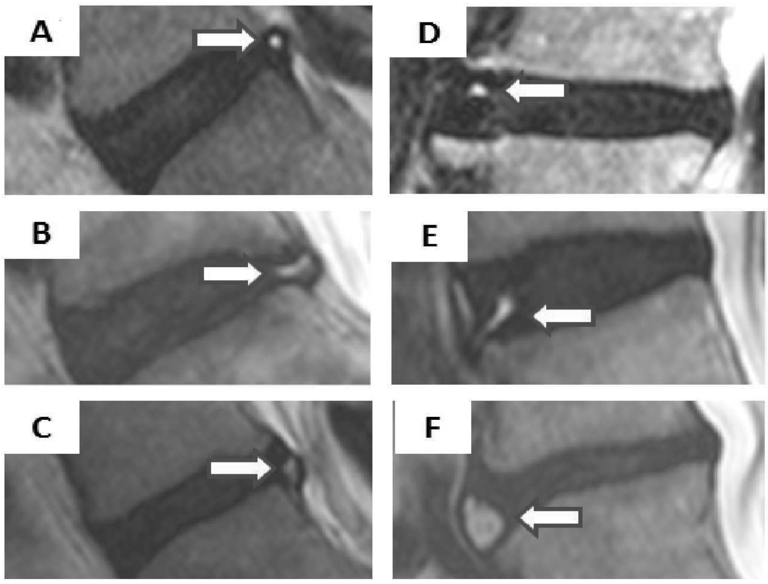

Fig 1. Classification of High Intensity Zones based on morphology and topography. High Intensity Zones (HIZ) were defined as a high intensity signal (white) surrounded by low intensity (black) located in the annulus fibrosus on T2-weighted sagittal MRI. Six types of HIZs were created based on the shape (round type, fissure type, vertical type, rim type, and giant type), and location within the disc (posterior or anterior). The images represent **(A)** posterior round type, **(B)** posterior fissure type, **(C)** posterior vertical type, **(D)** anterior round type, **(E)** anterior rim type, and **(F)** anterior enlarged type.

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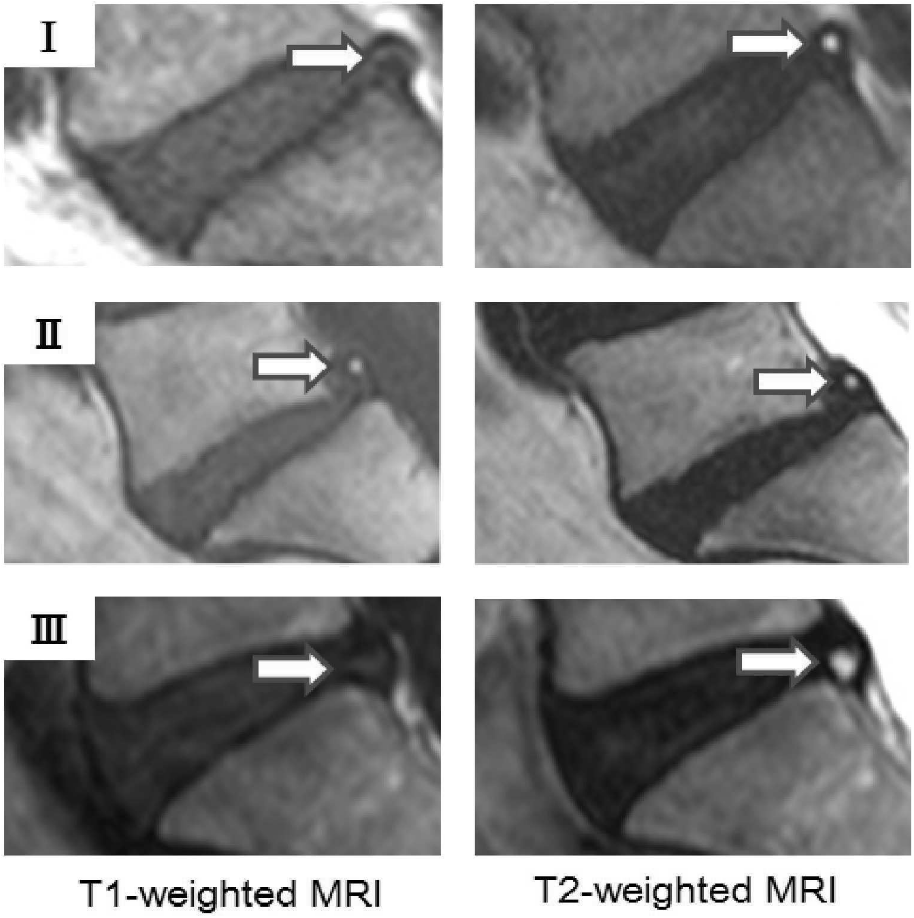

Fig 2. High Intensity Zones based on signal types on T1- and T2- weighted MRI. Three types of High Intensity Zones (HIZ) were created based on the signal type on T1-weighted MRI (low-intensity, high-intensity, and iso-intensity signal) and T2-weighted MRI (high-intensity signal). (I) T1-weighted low-intensity and T2-weighted high-intensity image, (II) T1-weighted high-intensity and T2-weighted high-intensity image, and (III) T1-weighted iso-intensity and T2-weighted high-intensity.

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RK). DD was classified by grade 4 or 5 on sagittal T2W MRI based on Pfirrmann's classification [41]. Disc displacement was evaluated as a disc bulge, protrusion, or extrusion. Disc bulge was defined as a disc displacement posteriorly beyond the line of the posterior edges of the adjacent vertebral bodies. Disc protrusion was noted as the nucleus displacement beyond the confines of the annulus fibrosus. Disc extrusion was recognized when the distance between the edges of the disc material beyond the disc space was greater than the distance between the edges of the base of the disc material beyond the disc space [42, 43]. Modic change was defined as diffuse areas of signal change along the endplates, and always parallel to the vertebral end plates on sagittal T1 and T2W images. Modic classification was based on the description originally proposed by Modic *et al* [44] on MRI: Type I was defined as decreased signal intensity on T1W and increased signal intensity on T2W, Type II change was defined as increased signal intensity on both T1W and T2W, and Type III change was defined as decreased signal intensity on both T1W and T2W. Endplate abnormality in any rostral or caudal endplate were assessed as SN defined as a local vertebral endplate defect/abnormality in deviation of the typical concavity or flattened continuous shape of the endplate [30,45]. The intra- and inter-observer reliabilities of these additional MRI phenotypes have been previously reported to be good to excellent [30, 39, 40].

Statistical analysis

All statistical analyses were performed using JMP version 8 (SAS Institute Japan, Tokyo, Japan). Prevalence of HIZ was examined both per subjects and per disc level. Presence of HIZ was defined as having at least one HIZ in the lumbar region. Moreover, we assessed the prevalence of HIZ regarding shape (round type, fissure type, vertical type, rim type, and enlarge type), location within disc (posterior or anterior), and signal types on T1W MRI of HIZ in the lumbar region and at each affected lumbar disc level, respectively. Pearson χ^2 test and ANOVA (analysis of variance) with within group Tukey post-hoc tests were used to assess the association between HIZ and no HIZ, between posterior HIZ and anterior HIZ, and among T1W low-, high-, and iso- intensity type of HIZ where applicable. Non-paired student t-test was performed to compare continuous Pfirrmann grade at HIZ affected disc level. The threshold for statistical significance was a p-value less than 0.05.

Results

There were 814 individuals who underwent lumbar MRI assessment, of which 246 were males (30.2%) and 568 were females (69.8%). The mean age of the subjects was 63.6 years (SD: ±13.1 years). The mean age of males was 63.1 years (SD: ±14.0 years) and the mean age of females was 63.8 years (SD: ±12.7 years). The mean height was 166.8 cm (SD: ±6.7 cm) in males and 153.3 cm (SD: ±6.4 cm) in females. The mean weight was 66.8kg (SD: ±11.0kg) in males and 53.1 kg (SD: ±9.0 kg) in females. In addition, the mean body mass index (BMI) was 24.0 kg/m^2 (SD: ±3.6 kg/m^2) in males and 22.6 kg/m^2 (SD: ±3.6 kg/m^2) in females.

Prevalence of HIZ

HIZ were noted in 38.0% (n = 309) of all participants, and within these subjects the prevalence of posterior HIZ, anterior HIZ, and both posterior/anterior HIZ in the overall lumbar spine were 47.3% (n = 146), 42.4% (n = 131), and 10.4% (n = 32), respectively. Of the 309 HIZ subjects, 26.0% had single HIZ (n = 212), 8.6% had 2 HIZs (n = 70), 2.7% had 3 HIZs (n = 22) and 6.1% had 4 HIZs (n = 5). Of these subjects, involved discs only had a single HIZ. In addition, of the 97 multilevel HIZ subjects, 71.1% had consecutive level HIZs (n = 69) and 26.9% had skipped level HIZs (n = 28). The overall percentage prevalence of posterior and anterior HIZ per lumbar levels is illustrated in Fig 3. Posterior HIZ was most common at L5/S1 followed by L4/5. Alternatively, anterior HIZ had the highest prevalence at L3/4 followed by L2/3. As such, region-specific variations between upper (L1-L4) and lower (L4-S1) lumbar spine HIZ were noted.

Morphology and topography of HIZ

Table 2 illustrated the morphological distributions of HIZs of the lumbar discs. Round type HIZ (Fig 1A and 1D) were most common in both posterior and anterior discs. Furthermore, round type HIZ in the posterior disc was more common at L4/L5 and L5/S1, whereas round type HIZ in the anterior disc was most common at L2/L3 and L3/L4. Fissure type and vertical type HIZ in the posterior disc (Fig 1B and 1C) was most common at L5/S1 and L4/L5. Rim type and enlarged type HIZ in the anterior disc (Fig 1E and 1F) were most common at L3/L4 and L4/L5. In addition, of the 309 subjects with HIZ, 222 (71.8%) had T1W iso-intensity type

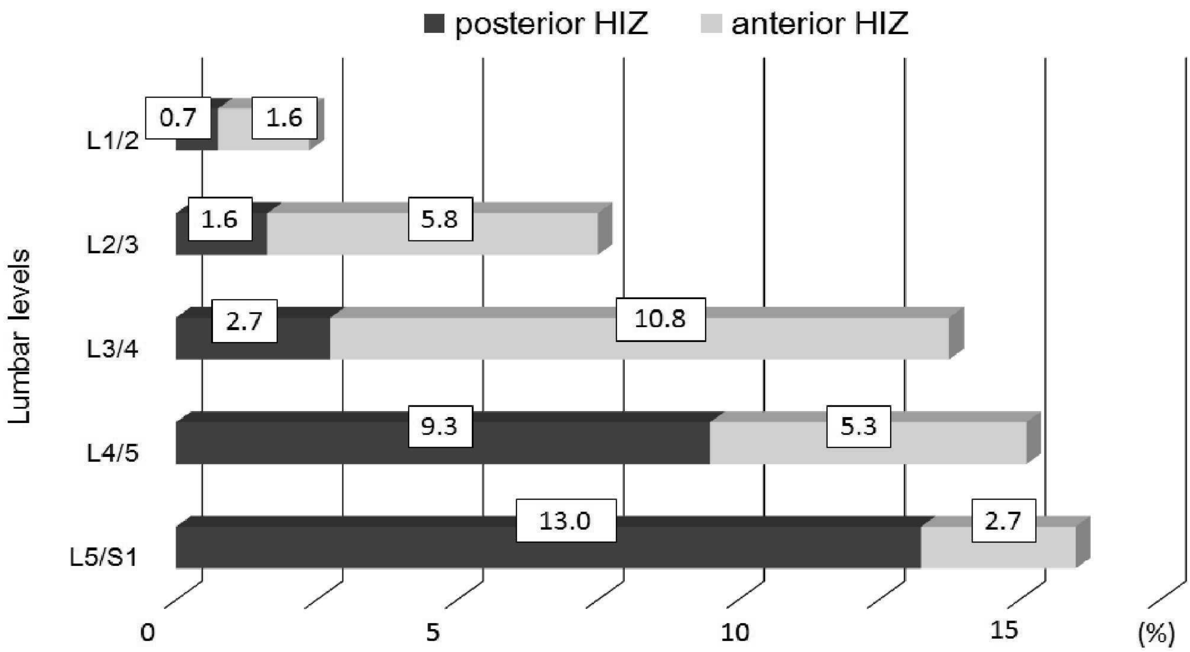

Fig 3. Bar chart showing the overall percent prevalence of anterior and posterior High Intensity Zones per lumbar level. Posterior HIZ was most common at L5/S1 followed by L4/5. Alternatively, anterior HIZ had the highest prevalence at L3/4 followed by L2/3.

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of HIZ (Fig 2 type III), followed by 66 (21.4%) with T1W high-intensity type of HIZ (Fig 2 type II) and 21 (6.8%) with T1W low-intensity type of HIZ (Fig 2 type I). As for disc level, T1W iso-intensity type of HIZ was most common at L4/L5 (11.5%, n = 94) followed by L5/S1 (11.4%, n = 93), T1W high-intensity type of HIZ was the highest at L5/S1 (3.7%, n = 30) followed by L4/L5 (2.9%, n = 24), and T1W low-intensity type of HIZ was the highest at L4/L5 (1.0%, n = 8) followed by L3/L4 (0.9%, n = 7).

Association of other spinal MRI phenotypes

As Table 3 illustrates the presence of HIZ was a clear determinant whether that disc level had other spinal MRI phenotypes or not. Disc levels with HIZ had significantly more disc bulges/protrusions (37.9% vs 29.3%, $p<0.01$) and DD (median 3.8, SD: ± 0.7 vs. 3.7, SD: ± 0.7, $p<0.001$), but not extrusions (1.1% vs 1.3%, $p = 0.97$). Modic type II change was significantly

Table 2. Distribution of shapes of High Intensity Zones at lumbar levels (n: 814 subjects).

Disc level	Posterior round, n (%)	Posterior fissure, n (%)	Posterior vertical, n (%)	Anterior round, n (%)	Anterior rim, n (%)	Anterior enlarged, n (%)
L1/L2	6 (4.0)	0 (0)	0 (0)	11 (7.5)	2 (3.7)	0 (0)
L2/L3	9 (6.0)	0 (0)	4 (6.2)	42 (28.8)	5 (9.3)	0 (0)
L3/L4	16 (10.6)	0 (0)	6 (9.2)	61 (41.8)	21 (38.9)	6 (40.0)
L4/L5	49 (32.5)	3 (42.9)	24 (36.9)	20 (13.7)	17 (30.9)	8 (53.3)
L5/S1	71 (47.0)	4 (57.1)	31 (47.7)	12 (8.2)	9 (16.4)	1 (6.7)
Total	151(100)	7 (100)	65 (100)	146 (100)	54 (100)	15 (100)

Note, every disc level from L1/L2 to L5/S1 has been individually evaluated.

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Table 3. Associated variables with High Intensity Zones at affected lumbar levels.

Variables	HIZ	No HIZ	p-value	Posterior HIZ	Anterior HIZ	p- value	T1W low-intensity type of HIZ	T1W high-intensity type of HIZ	T1W iso-intensity type of HIZ	p-value
Total discs; 4070	438	3632		223	215		22	80	339	
HIZ affected disc level										
Disc bulges/ protrusions, n (%)	166 (37.9)	1065 (29.3)	<0.01	96 (43.0)	70 (32.6)	<0.001	9 (41.0)	36 (45.0)	123 (36.3)	<0.01
Extrusions, n (%)	5 (1.1)	48 (1.3)	0.97	4 (1.8)	1(0.5)	0.33	0 (0)	2 (2.6)	3 (0.9)	0.52
Disc degeneration (mean ±SD)	3.8± 0.7	3.7±0.7	<0.001	3.8±0.7	3.6 ± 0.7	<0.001	3.7±0.8	3.9±0.7	3.8±0.6	<0.01
HIZ affected vertebral body adjacent to the end plate (total endplates;4070)										
Modic type I, n (%)	24 (5.5)	176 (4.9)	0.29	13 (5.8)	11 (5.1)	0.32	0 (0)	7 (8.8)	17 (5.0)	0.18
Modic type II, n (%)	122 (27.9)	779 (21.4)	<0.01	75 (33.6)	47 (21.9)	<0.001	7 (31.8)	22 (27.5)	94 (27.7)	<0.05
Modic type III, n (%)	14 (3.2)	88 (2.4)	0.18	13 (5.8)	1 (0.5)	<0.0001	0 (0)	3 (3.8)	11 (3.2)	0.4
Schmorl's node, n (%)	101 (23.1)	707 (19.5)	0.075	50 (22.4)	51 (23.7)	0.19	3 (13.6)	21 (26.3)	74 (21.8)	0.75

Pearson χ test and ANOVA (analysis of variance) with within group Tukey post-hoc tests were used to assess the association between HIZ and no HIZ, between posterior HIZ and anterior HIZ, and among T1W low-, high-, and iso- intensity type of HIZ where applicable. Non-paired student t-test was performed to compare continuous Pfirrmann grade at HIZ affected disc level. High-intensity zones (HIZ), T1W: T1-weighted, SD: standard deviation, %: percentage, n: number of subjects.

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associated with HIZ at the affected vertebral body adjacent to the end plate (27.9% vs. 21.4%, p<0.01).

Posterior HIZ had more bulges/protrusions (43.0% vs. 32.6%, p<0.001) and DD (median: 3.8, SD: ± 0.7 vs. 3.6, SD: ± 0.7, p<0.001) than anterior HIZ. Modic type II change was more significantly associated with posterior HIZ at each affected vertebral body (33.6% vs. 21.9%, p<0.001), Modic type III change was in comparison more significantly associated with posterior HIZ (5.8% vs. 0.5%, p<0.0001).

When comparing T1W low-intensity, T1W high-intensity and T1W iso-intensity types of HIZ, T1W low-intensity and high- intensity types of HIZ had more bulges/protrusions as compared with T1W iso-intensity type of HIZ (41.0% vs. 46.8% vs. 36.0% p<0.01) and DD (median: high 3.7, SD: ± 0.8 vs. low 3.9, SD: ± 0.7, vs iso 3.8, SD: ± 0.6, p<0.01). Modic type II change was significantly associated with T1W low-intensity type of HIZ than T1W iso- and high intensity types of HIZ (31.8% vs. 28.6% vs. 27.4%, p<0.05). (Table 3)

Discussion

Our large-scale population-based study presents a novel classification scheme of HIZ based upon evaluation of the morphology, topography, and the relationship of T1W and T2W MRI signal changes of HIZ. This classification is more precise and comprehensive than what has been traditionally reported and can be utilized for any future analysis regarding phenotype association and clinical relevance. Furthermore, to our knowledge, this study is also the first to address HIZ and their association of the other MRI spinal phenotypes based on both T1W and T2W MRI.

Since the original description of the HIZ on T2W sagittal MRI in 1992 [8], the prevalence of HIZ has varied greatly between reported studies in spite of the subjects with or without LBP. The prevalence of posterior HIZ was reported to be from 28.6% to 59% in symptomatic patients [8–11, 13] as compared to 3.2% to 24% in asymptomatic subjects [13–16]. Our large-scale population study in comparison showed that the prevalence of posterior HIZ was 21.9% (179/814 subjects). We also found posterior HIZ to be most common at L5/S1 (13.0%) followed by L4/L5 (9.3%), which was supported by a few studies [8, 10, 15]. However, we also report anterior HIZ to commonly occur at L3/L4 (10.8%) followed by L2/L3 (5.8%). This finding underscores the fact that region-specific variations of HIZ exists within the lumbar spine, with distinction between the upper (i.e. L1-L4) and lower (i.e. L4-S1) lumbar discs. Recent studies have noted more of a developmental origin or predisposition of upper lumbar segment phenotypes [46]. Nonetheless, the fact that HIZ is frequently found to be at the anterior of the disc is contrary to the traditional belief that HIZ must be posterior [8–18]. Hence, the lack of standardization for classifying HIZ for including anterior HIZ may be a likely reason for the discrepancies in the current literature regarding the reported prevalence.

Provocation discography has been utilized for assessment of annular tears and LBP [17, 18, 47, 48]. However, discography remains controversial due to the associated risks. For example, the procedure is invasive and complications include infection (epidural abscess, discitis), neurological injury, and possible contrast medium reaction [48, 49]. There is also the possibility of increased progression of DD and herniation after the examination [48, 49]. Therefore, to allow for future non-invasive HIZ research, Yu *et al* [17] reported the sensitivity of HIZ to diagnose annular tears on MRI with discography and cadavers and concluded that HIZ demonstrated some radial tears of annulus in 1989. With our more thorough MRI study with advanced sequences and imaging technique, our findings and classification of morphological/topographical variants of HIZ will further enhance our understanding of the pathology of intervertebral disc disorder. This allows us to have a more sensitive and non-invasive method of identifying symptomatic disc levels, predicting disc changes, and potential use for patient selection for disc regenerative therapies. This also has potential to be a marker for identifying patients at risk for adjacent segment degeneration/disease in relation to a fusion or arthroplasty procedure.

Various proposals have been put forward to explain the discrepancy between the presence of HIZs in asymptomatic and symptomatic individuals [8–16]. Six years after the initial paper [8], Bogduk postulated that annular tears may be present in asymptomatic subjects as low-intensity zones on T2W MRI, and these may become painful and assume a brighter signal to become an "activated" HIZ [50]. Indeed, the present study is in concurrence as we did not find low intensity zones on T2W MRI. Bogduk also reported an inability to detect HIZ on T1W MRI [8]. However, this is disputed in our study as we observed variable intensity types of HIZ on T1W MRI. Hence, we believe that coupling of T2W and T1W MRI sequences is necessary to define the HIZ phenotype. HIZ has been defined as collections of mucoid fluid within the annulus tear and thus have a bright signal on T2W MRI in the pathological studies [8, 10, 14]. However, HIZ may also change and represent a reflection in the pathological process, which may convert from one type to another, for example, neovascularization of annulus, a healing annular tear, and fluid or mucoid material filled in the inflamed annular tear. These processes may express as different signals on T1W MRI.

We found in this study significant associations between the presence of HIZ and DD, disc bulge/protrusion and Modic type II changes at all affected levels. These results support the view that degenerative findings and HIZ co-exist. Some investigators have suggested that HIZ was a part of the degenerative process as HIZs occurred in association with degenerative changes within the disc [9,10,13], whereas others disagreed [14]. This discrepancy is partly explained by the sample population, presence or not of symptoms and how clinical parameters are defined, small sample size, and/or insufficient statistical analyses. However this large-scale, population-based study identified a strong association between HIZ with DD and disc bulge/ protrusion. We also found that Modic Type II changes were more associated with the presence of HIZ, especially posterior HIZ, T1W low-intensity type of HIZ. In addition, Modic type III change was more associated with posterior HIZ than anterior HIZ. These relationships are understandable and can be attributed to the altered biomechanics associated with endplate failure caused by HIZ or as a reverse causality of Modic changes leading to HIZ. Furthermore, Schmidt *et al* [51] showed that HIZ was associated with instability of the intervertebral disc which caused fluid to move through annular tear into the outer annulus [15]. Subsequently, the unstable motion of intervertebral disc increased the stress and strain at adjacent disc segments, leading to Modic change [52]. Thus, HIZ and its sub-phenotypes may have potential as imaging biomarkers to identify those patients at risk for DD, instability of disc, and adjacent segment degeneration/disease. In general, studies have noted that Modic changes are highly associated with LBP; however, different degrees of pain severity and disability may exist [4–6]. There are also subjects with Modic changes and no HIZ. As such, being able to identify clinically relevant HIZ associated with Modic changes may shed additional light into identifying more problematic disc levels.

These results of our study may be influenced by the high age groups of our cohort (mean age over 60 years); thus, additional study is necessary to further assess HIZ among different age strata. Moreover, as with all population-based studies, there may be an effect of ethnic variability that should be addressed in future studies [53]. In addition, due to the availability of scanning units at the initiation of our study, we utilized a mobile 1.5 T MRI unit to facilitate the assessment of our subjects. Although a higher field strength, such as 3T MRI, may theoretically have a higher sensitivity in detecting specific HIZs; there have been no studies that have addressed such a concern to date to gauge the extent of the variation and it was not an aim of our current study. However, it is also important to consider that all subjects in our current study were assessed via the 1.5T MRI, representing a consistency in assessment. Our work raises awareness of the variation of HIZs that may exist in the lumbar spine and we hope will form the much needed foundation for future studies to explore upon this research platform to a much greater extent. Finally, the current study did not address an association of HIZ with LBP due to the limited pain profile assessment available in the cohort. Importantly, the strength of the present study is the size of the study population and the novel in-depth multiparametric phenotype profiling on MRI that could serve as the basis for future HIZ study and phenotype standardization in the future. Such a foundation can then be utilized to assess more in-depth clinical relevance and utility.

Conclusions

This is the first large-scale, population-based study to systematically assess the epidemiology of HIZ on 1.5T MRI and report upon a novel classification of this phenotype in the lumbar spine. In addition, this study is also the first to utilize a multi-parametric imaging approach to assess the different variants of HIZ by the use of T2W and T1W MRI. Hence, with such alternative imaging in mind, it may be appropriate in the future to not refer to the HIZ phenotype as representing "high" intensity zones but rather "intensity zones". Such a nomenclature may be more apropos given that some HIZ on T1W MRI are not "high" intensity. Although HIZ is frequently found to be posterior, as traditionally believed, they do occur anteriorly in the disc, and numerous morphological variants exist that are disc-level and region-specific, and distinguishable via a multi-parametric imaging approach. Furthermore, HIZ are highly associated with specific MRI spinal phenotypes, such as DD, disc bulges/protrusions, and Modic changes. In an age whereby various "omics" approaches and large data set cohorts are becoming more commonplace, a standardized phenotype classification of HIZ is imperative. Such a scheme can be further utilized to assess the clinical profile of patients, identify problematic discs, prognosticate outcomes and help tailor specific spine treatments. Additional, large-scale, comparative prospective studies are needed to further validate our findings and address their clinical impact.

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Author Contributions

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Contributed reagents/materials/analysis tools: MT DS JC.

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RESEARCH ARTICLE

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Locomotive syndrome is associated with body composition and cardiometabolic disorders in elderly Japanese women

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Abstract

Background: A concept referred to as locomotive syndrome (LS) was proposed by the Japanese Orthopaedic Association in order to help identify middle-aged and older adults who may be at high risk of requiring healthcare services because of problems associated with locomotion. Cardiometabolic disorders, including obesity, hypertension, diabetes, and dyslipidemia, have a high prevalence worldwide. The purpose of this study was to determine the associations between LS and both body composition and cardiometabolic disorders.

Methods: The study participants were 165 healthy adult Japanese women volunteers living in rural areas. LS was defined as a score ≥16 on the 25-question Geriatric Locomotive Function Scale (GLFS-25). Height, body weight, body fat percentage, body mass index (BMI), and bone status were measured. Bone status was evaluated by quantitative ultrasound (i.e., the speed of sound [SOS] of the calcaneus) and was expressed as the percent of Young Adult Mean of the SOS (%YAM). Comorbid conditions of hypertension, hyperlipidemia, and diabetes were assessed using self-report questionnaires.

Results: Twenty-nine participants (17.6 %) were classed as having LS. The LS group was older, shorter, and had a higher body fat percentage, a higher BMI, and lower bone status than the non-LS group. Multiple logistic regression analysis showed that participants with a BMI ≥23.5 kg/m^2 had a significantly higher risk for LS than those with a BMI <23.5 kg/m^2 (odds ratio [OR] = 3.78, $p < 0.01$). Furthermore, GLFS-25 scores were higher in participants with than those without hypertension, diabetes, or obesity, and significantly increased with the number of present disorders.

Conclusions: These findings suggest that BMI may be a useful screening tool for LS. Furthermore, because hypertension and diabetes were associated with LS, the prevention of these disorders accompanied by weight management may help protect against LS.

Keywords: Body composition, Locomotive syndrome, Bone mass index, Cardiometabolic disorders

Background

Japan is rapidly transforming into a super-aged society. The Japanese Statistics Bureau reported that as of 2015, individuals aged 65 years or older comprised 26.2 % of the Japanese population [1]. Parallel with this transformation is an increase in the incidence of health issues such as stroke, senility, dementia, falls, fractures, and joint disorders, and in turn, the number of individuals requiring nursing care [2].

Maintaining a healthy locomotive system, which includes the bone, cartilage, muscle, and nervous systems, is the foundation of increased disability-free life expectancy. It follows that, from a public health perspective, preventing the deterioration of motor function is an issue that requires urgent attention. Therefore, an epidemiological concept referred to as locomotive syndrome (LS) [2, 3] has been proposed by the Japanese Orthopaedic Association (JOA). LS primarily affects elderly individuals who currently require nursing care services owing to problems involving the locomotive system or those who have risk conditions that will likely necessitate such services in the

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future [4]. LS is caused by the reduced muscle strength and balance associated with aging and locomotive pathologies including osteoporosis, osteoarthritis (OA), and sarcopenia [2]. In females, LS may also be caused by the decreasing levels of physical activity and bone mineral density (BMD) that tend to occur after menopause. The incidence of LS increases with age, and is significantly higher in women (35.6 %) than in men (21.2 %) [5, 6]. As beneficial locomotive exercises for the prevention of LS, the JOA recommends performing “half-squats” and “unipedal standing balance exercises with open eyes” [3].

The 25-question Geriatric Locomotive Function Scale (GLFS-25), a quantitative and evidence-based screening tool, can be used to identify individuals with LS [7, 8]. A previous study reported finding a Spearman’s correlation coefficient of 0.85 ($p < 0.001$) for the association between GLFS-25 scores and the European Quality of Life 5 Dimensions Index (EQ-5D), indicating that the GLFS-25 had excellent concurrent validity [7].

Identifying factors associated with the development of LS is crucial for its prevention. Results from a number of recent studies suggest that GLFS-25 scores strongly correlate with several physical performance measures, including the unipedal standing balance and Timed Up And Go tests [5, 9–13]. However, only a few reports [5, 14] have focused on the association between the development of LS and body composition, even though numerous studies have reported that weight, body fat percentage, and BMD are associated with cardiovascular disease, various cancers, osteoporosis, hypertension, diabetes and hyperlipidemia [15–21].

An association was recently reported between abdominal obesity and LS in elderly Japanese women, suggesting that waist circumference may be useful measure to assess the risk for LS [22].

Metabolic syndrome comprises a combination of medical disorders, including increased fasting plasma glucose, abdominal obesity, high triglyceride levels, and high blood pressure, that increase the risk of developing metabolic conditions and cardiovascular disease [23]. In conjunction with metabolic syndrome, obesity, hypertension, diabetes, and dyslipidemia, which are known as the “deadly quartet,” have a high prevalence worldwide [24]. Many studies have reported that physical activity and body components are associated with metabolic syndrome [17–21]. The proportion of the Japanese population with LS (47 million) is estimated to be more than twice that with metabolic syndrome (20 million) [25, 26].

In the present study, we evaluated body composition using body mass index (BMI), body fat percentage, and bone status, and hypothesized that these variables would be predictive of GLFS-25 scores. Confirmation of this hypothesis would indicate that, in addition to sports performance training, control of body composition could be used to prevent LS. Therefore, the purpose of this study was to determine the association between body composition and LS, the threshold values of body composition measures for discriminating between individuals with and without LS, and the OR of LS according to body composition above or below these thresholds in elderly Japanese women living in rural areas. An additional objective was to determine the association between LS and cardiometabolic disorders.

Methods

Participants

This study was conducted in a rural area (Tanabe city, Wakayama Prefecture, Japan) between January 2013 and March 2015. The study inclusion criteria were as follows: 1) Japanese women, age > 60 years; 2) ability to walk independently; and 3) living at home and being capable of self-care. All participants initially underwent body composition measurements, in the order of height, weight, and body fat percentage, followed by an evaluation of LS status at a public hall where a “Lecture meeting and checkup for health” was held with support from the local government. Afterwards, 198 women were asked to complete a self-report questionnaire at home regarding comorbid conditions and then to return the questionnaire by mail. A stamped envelope was provided to encourage the return of the questionnaire. A total of 165 women underwent the measurements and returned the questionnaire (mean age ± standard deviation, 68.8 ± 6.1 years; range, 60–83 years).

Measurement of variables

Body weight and body fat percentage were measured using the KaradaScan Body Composition Monitor with Scale (HBF-362; Omron Co., Kyoto, Japan) while participants were wearing normal indoor clothing. The procedure was performed with the participants standing barefoot on a metal surface in accordance with the manufacturer’s instructions. BMI was calculated as weight divided by the square of height, and obesity was defined as BMI ≥25 kg/m^2 in accordance with the guidelines of the Japan Society for the Study of Obesity [27]. Bone status was assessed using speed of sound (SOS) measured using a quantitative ultrasound (QUS) device (Canon Life Care Solutions Inc., CM-200, Osaka, Japan) at the calcaneus of the dominant foot while the participants were barefoot and seated. QUS, which has a number of advantages, including portability, low cost, and a lack of exposure to radiation [28], enables the evaluation of bone quality, especially the microarchitecture at the calcaneus, and is useful for predicting risk for future fracture [29]. Bone status was shown as the percent of Young Adult Mean of the SOS (%YAM) [30]. It has been reported that calcaneal QUS parameters reflect the characteristics of the trochanteric area of the proximal hip, although these values are not specifically reflective of values of the femoral neck or shaft [31].

Evaluation of LS

LS status (presence and degree) was evaluated based on GLFS-25 scores (Additional file 1). The GLFS-25 is a self-report questionnaire composed of the following 25 items focusing on the month before completing the measure: four questions on pain; 16 on activities of daily living; three on social function; and two on mental health status [7]. These 25 items are scored from 0 (no impairment) to 4 (severe impairment), with a total score range from 0 to 100. Higher scores indicate worse locomotive function. The cutoff score for LS, as determined by receiver operating characteristic (ROC) analysis, is 16 points [7].

Comorbid conditions

Comorbid conditions of hypertension, hyperlipidemia, and diabetes were assessed using the following question on the self-report questionnaire: "Do you presently take medication for hypertension, diabetes, or hyperlipidemia?"

Statistical analysis

Participants were classified as LS (≥16) or non-LS (<16) based on GLFS-25 scores, and then independent variables were compared between groups. For numerical variables, normality of distribution and homogeneity of variance were tested before across-group comparisons. When the assumptions of normal distribution and homogeneity of variance were met in both groups, we performed the student t-test, and when the assumption of normal distribution was met, but not the assumption of homogeneity of variance, we performed Welch's t-test. When the data were non-normally distributed, the Wilcoxon signed-rank test was used.

ROC analysis was used to evaluate the threshold of each body composition measure (BMI, body fat percentage, and %YAM) in order to discriminate the LS from the non-LS group. An area under the ROC (AUC-ROC) curve of 1.00 was taken to indicate perfect discrimination, whereas an AUC-ROC of 0.50 was taken to indicate the complete absence of discrimination.

Multiple logistic regression analysis was performed to evaluate the age-adjusted significance of the prevalence of LS. The chi-square test was used for comparison of prevalence or number of cardiometabolic disorders between non-LS and LS. The Wilcoxon signed-rank test was used for comparison of GLFS-25 scores classified by with and without cardiometabolic disorders, as well as by the number of present disorders. Statistical analysis was conducted using JMP 11 (SAS Institute, Cary, NC). All statistical tests were 2-tailed, and a significance level of 0.05 was used.

Results

Age, height, body weight, body fat percentage, BMI, bone status, GLFS-25 score, and the prevalence of components of cardiometabolic disorder are shown in Table 1. Twenty-nine participants (17.5 %) had a GLFS-25 score ≥16 and were thereby classified as LS (Table 2). The LS group was older and shorter than the non-LS group, and had a higher body fat percentage, a higher BMI, and lower bone status (Table 2).

ROC analysis was conducted for each body composition measure, and the threshold for discriminating the non-LS and LS groups was identified. This threshold was 37.3 % for body fat percentage, 23.5 kg/m^2 for BMI, and 73 % for %YAM (Table 3). ORs for the prevalence of LS according to the threshold values are shown in Table 4. High BMI was a significant risk factor for LS, with an OR of 3.78 as determined by multiple logistic regression analysis.

Figure 1 shows GLFS-25 scores classified by the presence or absence of each metabolic syndrome component (hypertension, diabetes, hyperlipidemia, and obesity). GLFS-25 scores were higher in participants with than without hypertension or diabetes, and in obese than in non-obese participants. Figure 2 shows GLFS-25 scores classified by the number of present cardiometabolic disorders. The results showed that GLFS-25 scores significantly increased with the number of cardiometabolic disorders ($p < 0.01$). Table 5 shows a comparison of the prevalence or number of cardiometabolic disorders between non-LS and LS subjects. The prevalence of LS was higher in participants with than without hypertension ($p < 0.05$) and obesity ($p < 0.01$).

Discussion

Association between body composition and LS

LS was proposed by the JOA in 2007 in order to identify individuals at high risk of requiring nursing care owing

Table 1 Characteristics of the study participants

Variables for components	Mean (SD[a])
Age (years)	68.8 (6.1)
Height (cm)	150.4 (11.9)
Weight (kg)	52.9 (8.3)
Body fat percentage (%)	33.9 (4.5)
BMI (kg/m^2)	23.1 (3.6)
%YAM[b] (%)	69.8 (11.0)
GLFS-25 score (points)	10.0 (10.3)
Components of cardiometabolic disorders	Prevalence (%)
Obesity	45 (27.3)
Hypertension	59 (35.8)
Diabetes mellitus	12 (7.3)
Hyperlipidemia	23 (13.9)

[a] *SD* standard deviation
[b] *YAM* percent of Young Adult Mean of the speed of sound of the calcaneus

Table 2 Comparison of characteristics between non-locomotive and locomotive syndrome[a]

Variables	Non-LS[b] ($n = 136$)	LS[c] ($n = 29$)	p value
Age (years)	68.1(5.9)	72.1(6.0)	0.0014[e]
Height (cm)	151.9(5.0)	143.7(25.5)	0.0015[e]
Weight (kg)	52.3(8.3)	55.4(8.3)	0.0730[f]
Body fat percentage (%)	33.4(4.3)	36.3(4.6)	0.0020[e]
BMI (kg/m^2)	22.7(3.1)	25.2(3.7)	0.0007[e]
%YAM[d] (%)	70.6(11.4)	65.7(8.3)	0.0288[f]

[a]Locomotive Syndrome: GLFS-25 score ≥16 points
[b]*Non-LS* non-locomotive syndrome
[c]*LS* locomotive syndrome
[d]*YAM* percent of Young Adult Mean of the speed of sound of the calcaneus
[e]Wilcoxon signed-rank test was applied for age, height, body fat percentage, and BMI
[f]Student's t-test was applied for weight and YAM

to problems associated with the locomotive system [2]. The GLFS-25 was subsequently developed to measure the presence and degree of LS in Japanese individuals [7]. However, since its implementation, the GLFS-25 cutoff value for identifying individuals with LS has been determined in accordance with health-related quality of life [7, 11]; therefore, information on the association between GLFS-25 scores and body composition is limited. Therefore, the primary purpose of this study was to determine the association between LS as defined by GLFS-25 scores and body composition measures in elderly Japanese women.

Our results showed that participants with LS were shorter, had a higher body fat percentage, a higher BMI, and lower bone status than participants without LS. Previous studies have reported similar results in middle-aged and elderly Japanese women [5, 14]. Muramoto et al. found that GLFS-25 scores had a significant positive correlation with body fat percentage and BMI, a negative correlation with body height and BMD, and no correlation with body weight according to correlation analysis [5].

Based on comparative analysis, participants with LS have been shown to have significantly greater BMI and body fat percentage and lower height than those without LS, whereas no significant difference has been observed in body weight or BMD [14].

Table 3 Threshold values of age and body composition for locomotive syndrome

	Threshold values	AUC[a]	Sensitivity (%)	Specificity (%)
Body fat percentage (%)	37.3	0.68	51.72	68.13
BMI (kg/m^2)	23.5	0.70	72.41	67.29
%YAM[b] (%)	73.0	0.61	86.21	79.23

[a]*AUC* area under the curve
[b]*YAM* percent of Young Adult Mean of the speed of sound of the calcaneus

Table 4 Evaluation of odds ratios for locomotive syndrome according to body composition

	Above or below the threshold value	Odds ratio (95 % CI[a])	P value
Body fat percentage (%)	<37.3	1	0.3584
	≥37.3	1.62 (0.58–5.00)	
BMI (kg/m^2)	<23.5	1	0.0087
	≥23.5	3.78 (1.39–11.07)	
%YAM[b] (%)	<73	1.68 (0.65–4.73)	0.2900
	≥73	1	

[a]*CI* confidence interval
[b]*YAM* percent of Young Adult Mean of the speed of sound of the calcaneus
Data were adjusted by age

In the present study, we found that participants with LS were shorter than those without LS. Shorter height has been reported to be significantly associated with fear of falling in elderly Japanese individuals [32]. Shorter height may be caused by an age-related change in the curvature of the spine or atrophy of trunk extension muscles, which can decrease postural control. A reduction in postural control can cause fear of falling or a decline in the amount of physical activity [33]. Therefore, we propose that the LS group included more participants that had lost height due to a change in the curvature of the spine or atrophy of trunk extension muscles than the non-LS group, and therefore had less postural control and engaged in fewer activities in daily life, which increased their risk for developing LS.

The present results showed that participants with LS had a higher body fat percentage than those without LS. Increased body fat causes more mechanical stress in weight-bearing joints and promotes the degeneration of joint tissue through the production and release of adipokines [34]. Adipokines are derived from adipocytes and may upregulate receptor activators of nuclear kappa B ligand, leading to increased bone resorption and reduced BMD [35]. Participants with a higher body fat percentage may have secreted more adipocytes, and this may have had a negative influence on the movement of the joints, thereby increasing the risk of LS.

The present study showed that a BMI ≥23.5 k/m^2 was significantly associated with LS, with an OR of 3.78 as identified by multiple logistic regression analysis. The Japan Society for the Study of Obesity defines the cutoff for obesity as a BMI 25 kg/m^2 [8]. In the present study, the mean BMI of the participants with LS was ≥25 kg/m^2. Furthermore, GLFS-25 scores were higher in obese than in non-obese participants (Fig. 2d). LS is closely associated with age-related skeletal disorders such as osteoporosis, OA, lumbar spinal stenosis (LSS), degenerative spinal disease and sarcopenia [4]. Furthermore, obesity is a risk factor for these disorders because mechanical overload on weight-bearing joints can activate chondrocytes, accelerate the degeneration of cartilage, and increase static compressive loading and

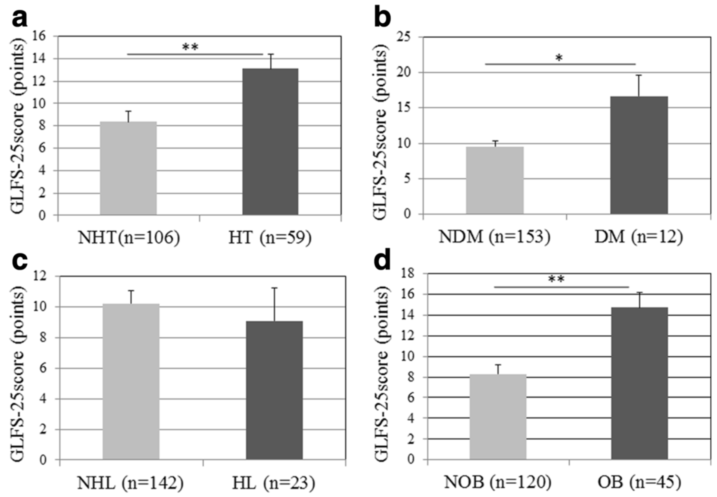

Fig. 1 GLFS-25 scores in participants with and without hypertension (**a**), diabetes (**b**), hyperlipidemia (**c**), and obesity (**d**). HT, hypertension; NHT, non-hypertension; DM, diabetes mellitus; NDM, non-diabetes mellitus; HL, hyperlipidemia; NHL, non-hyperlipidemia; OB, obesity (BMI ≥25 kg/m^2); NOB, non-obesity (BMI <25 kg/m^2); *$p < 0.05$; **$p < 0.01$; error bars, standard deviation

pressures associated with postures that damage disc integrity [36–38]. Moreover, it has been proposed that metabolic factors, including inflamed adipose tissue, dyslipidemia, oxidative stress, endothelial dysfunction and leptin dysregulation, as well as the clustering of these factors in metabolic syndrome, may play a crucial role in obesity-induced OA [39–41]. These findings support the present results regarding the association between obesity and LS.

Association between LS and cardiometabolic disorders

Obesity, hypertension, diabetes, and dyslipidemia are known as the "deadly quartet" [24]. Numerous studies have reported that BMD is associated with these disorders [17–21]. The second purpose of the present study was to determine the association between LS and cardiometabolic disorders. Our results showed that LS is associated with hypertension, diabetes, and overweight, as well as with higher BMI. Furthermore, GLFS-25 scores significantly increased with the number of present cardiometabolic disorders.

There are some reports on the association between cardiometabolic disorders and OA. Some evidence suggests

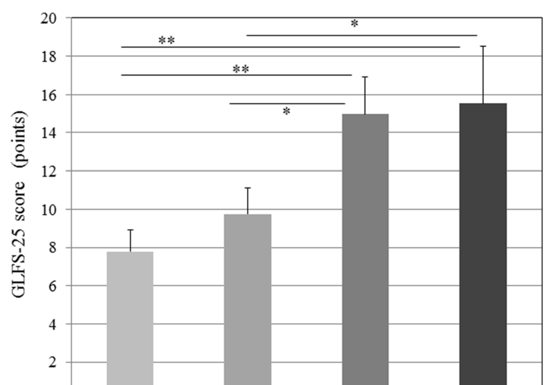

Fig. 2 GLFS-25 scores in participants with 0, 1, 2, and ≥3 present cardiometabolic disorders. A significant main effect was observed for the number of disorders ($p < 0.01$; analysis of variance). *$p < 0.05$; **$p < 0.01$; error bars, standard deviation

Table 5 Comparison of prevalence or number of present cardiometabolic disorders between non-locomotive and locomotive syndrome[a]

		Non-LS[b]	LS[c]	*P* value
NHT[d] (153)		128 (83.7 %)	25 (16.3 %)	0.0482
HT[e] (12)		8 (66.7 %)	4 (33.3 %)	
NDM[f] (142)		116 (81.7 %)	26 (18.3 %)	0.1364
DM[g] (23)		20 (87.0 %)	3 (13.0 %)	
NHL[h] (106)		92 (86.8 %)	14 (13.2 %)	0.5382
HL[i] (59)		44 (74.6 %)	15 (25.4 %)	
NOB[j] (120)		106 (88.3 %)	14 (11.7 %)	0.0011
OB[k] (45)		30 (66.7 %)	15 (33.3 %)	
Number of cardiometabolic disorders	0 (76)	67 (88.2 %)	9 (11.8 %)	0.0526
	1 (52)	44 (84.6 %)	8 (15.4 %)	
	2 (26)	18 (69.2 %)	8 (30.8 %)	
	≥3 (11)	7 (63.6 %)	4 (36.4 %)	

[a]Locomotive Syndrome: GLFS-25 score ≥16 points; [b]*Non-LS* non-locomotive syndrome, [c]*LS* locomotive syndrome, [d]*NHT* non-hypertension, [e]*HT* hypertension, [f]*NDM* non-diabetes, [g]*DM* diabetes, [h]*NHL* non-hyperlipidemia, [i]*HL* hyperlipidemia, [j]*NOB* non-obesity (BMI <25 kg/m^2), [k]*OB* obesity (BMI ≥25 kg/m^2)

that metabolic factors such as type 2 diabetes mellitus and elevated glucose concentration are associated with the development and progression of OA [40, 42]. In particular, the advanced glycation end products in cartilage collagen seem to be associated with both the senescent cartilage matrix and reduced chondrocyte function [43]. The presence of advanced glycation end products associated with the expression of advanced glycation end-product receptors in the cartilage collagen results in the increased production of matrix metalloproteinase and the modulation of the chondrocyte phenotype to hypertrophy and OA [44, 45].

OA and hypertension have been shown to frequently coexist [46]. The proposed mechanism of the development of OA with hypertension is as follows: narrow and/or constricted vessels restrict blood flow to subchondral bone, impairing circulation and nutritional supply to overlying articular cartilage, which ultimately contributes to the deterioration of cartilage in OA [47].

Mutual relations exist between the occurrence and presence of musculoskeletal diseases, particularly knee OA and cardiometabolic disorders [48]. Yoshimura et al. suggested that metabolic risk factors such as overweight, hypertension, hyperlipidemia, and impaired glucose tolerance increase the risk of occurrence and progression of knee OA [49, 50]. Recent reports have indicated that waist circumference, back muscle strength, and spinal inclination angle are important risk factors for LS [22]. In the present study, we demonstrated that LS is associated with hypertension and obesity, as well as a higher BMI. Furthermore, GLFS-25 scores significantly increased with the number of present cardiometabolic disorders. These findings suggest a close relationship between the locomotive system and cardiometabolic organs.

The proportion of adults with BMI >25 kg/m^2 has significantly increased worldwide [51]. The present findings contribute to the identification of factors that may prevent locomotive disorder and metabolic syndrome, particular in Western societies, in which many patients have metabolic syndrome. Although the concept of LS is currently used only in Japan, we believe it will become more common worldwide as the population continues to age.

The results of the present study suggest that BMI might be a useful measure for the simple detection of LS. Furthermore, hypertension and diabetes were found to be associated with LS. Weight management and prevention of these disorders may help protect against LS in elderly women. Elderly men should be included in future studies.

Limitations and future research

This study did have several limitations. First, the sample size of 165 was small; this number only represents about 1.2 % of all women aged between 60 and 83 years in Tanabe city. Furthermore, no significant relationship was found between LS and dyslipidemia; this may have been due in part to a lack of statistical power. Second, because the participants in this study were all Japanese women, care should be taken in generalizing the results to men or other ethnic groups. Third, data from a cross-sectional study are not sufficient to determine whether a causal relationship exists between BMI, LS, and cardiometabolic disorders. LS may cause obesity or hypertension and diabetes because it limits physical activity. Conversely, these cardiometabolic disorders may lead to the development of LS. It is therefore crucial to perform longitudinal studies to clarify the causal relationships among these factors. Fourth, comorbid conditions were only assessed using self-report questionnaires; therefore, blood pressure, blood glucose concentration, and blood lipid concentration measurements were not controlled. Thus, untreated participants with comorbid conditions may have been excluded from analysis; however, this possibility is low because participants attending the "Lecture meeting" would have been expected to have relatively high health awareness. Fifth, further research in larger-sized studies should measure lean mass because it is an important component of BMI. It is possible that BMI underestimates body fat percentage in clinical populations [52].

Conclusion

BMI, body fat percentage, and bone status were significantly associated with LS. In particular, a BMI ≥23.5 k/m^2 was significantly associated with LS. Moreover, GLFS-25 scores were higher in participants with a BMI ≥25 kg/m^2, hypertension, and diabetes than in the respective comparison groups. These results suggest that BMI is an important measure for the detection of LS. Furthermore, weight management and the prevention of metabolic syndrome may reduce the risk for LS.

Additional file

Additional file 1: The 25-question Geriatric Locomotive Function Scale [7]. (DOCX 154 kb)

Abbreviations

%YAM: Percent of Young Adult Mean of the SOS; AUC: area under the curve; BMD: Bone mineral density; BMI: Body mass index; GLFS-25: 25-question Geriatric Locomotive Function Scale; JOA: Japanese Orthopaedic Association; LS: Locomotive syndrome; OA: Osteoarthritis; OR: odds ratio; QUS: qualitative ultrasound; ROC: Receiver operating characteristic; SOS: speed of sound

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Availability of data and materials

The datasets analyzed in the current study are available from the corresponding author on reasonable request.

Authors' contributions
MN participated in the study design, performed the statistical analysis, and drafted the manuscript; YK provided assistance in the statistical analysis; RK, SN, AM, and HU performed measurements of variables; HH, HO, and MY provided assistance in the literature review and revised the manuscript; All authors read and approved the final manuscript.

Competing interests
The authors declare that they have no competing interests.

Consent for publication
Not applicable.

Ethics approval and consent to participate
All subjects provided written informed consent to use their data in the study. The study protocol was approved by the Ethics Committee of Wakayama Medical University (Reference No. 1005). This study was performed in accordance with the Declaration of Helsinki.

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Development of a Japanese version of the Somatic Symptom Scale-8: Psychometric validity and internal consistency

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ABSTRACT

Objective: We aimed to psychometrically validate the Japanese version of the Somatic Symptom Scale-8 (SSS-8) in Japanese individuals.
Method: Data were collected from Japanese individuals aged 20–64 years, who were recruited online, in February 2015. The scale reliability and validity were analyzed.
Results: Data from 52,353 individuals were analyzed. Cronbach's alpha for the assessment of internal consistency reliability was 0.86 for the total score. The concurrent validity results showed strong correlations with three domains of the Profile of Mood States-Brief form ($\rho = 0.51$–0.61) and the EuroQol 5 Dimension ($\rho = -0.54$). The known-group validity results indicated a linear trend in the severity of depression stratified using the Patient Health Questionnaire-2 (Jonckheere-Terpstra test, $p < 0.001$). Regarding convergent and discriminant validities, all items correlated most strongly with their own domains (coefficients ≥ 0.5), except for one item (headaches). Scores on perceived stress, pain, and general health differed across five SSS-8 severity groups (Steel-Dwass test, $p < 0.001$), expect for one group pair in health.
Conclusion: The Japanese version of the SSS-8 was valid with good internal consistency. This questionnaire could help detect somatic symptom burdens of chronic and severe musculoskeletal pain for primary prevention.

1. Introduction

Somatic symptoms are generally considered manifestations of an underlying psychiatric illness, such as anxiety, depression, or common mental disorders [1]. Common symptoms include various types of pain (e.g., back pain, joint pain, headache), gastrointestinal symptoms (e.g., food intolerance, regurgitation of food, bloating), cardiopulmonary symptoms (e.g., sweating, palpitation, breathlessness), and excessive tiredness [2]. Somatic symptoms are associated with deterioration of quality of life and psychological distress and increased use of health care services [3,4].

The Somatic Symptom Scale-8 (SSS-8) is a self-administered questionnaire assessing somatic symptom burden [5]. The SSS-8 consists of eight items that assess the following symptoms: stomach or bowel problems; back pain; pain in your arms, legs, or joints; headaches; chest pain or shortness of breath; dizziness; feeling tired or having low energy; and trouble sleeping. These items comprise the four symptom domains of gastrointestinal, pain, cardiopulmonary, and fatigue. Respondents rate how much each symptom has bothered them during the previous 7 days and score each item from 0 to 4: not at all (0), a little bit (1), somewhat (2), quite a bit (3), and very much (4), with no reverse-coded items included. The total score, ranging from 0 to 32, is a simple sum of each item score: a higher score indicates more severe somatic symptom burden.

The SSS-8 was originally developed in English as an abbreviated version of the Patient Health Questionnaire-15 (PHQ-15) [4], a questionnaire used worldwide to assess the presence and severity of somatic symptoms [6–11]. The PHQ-15 was used as a reference measure in the Diagnostic and Statistical Manual of Mental Disorders (Fifth Edition) (DSM-5) field trials to facilitate the diagnosis of somatic symptom disorder [12]. The German version of the SSS-8 has been linguistically and

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psychometrically validated and has shown good reliability and validity for the general German population [5] as well as psychometric equivalence to the PHQ-15 [13]. Whereas the PHQ-15 has been used internationally, the SSS-8 is newly developed but is expected to be a useful tool in busy medical settings because it requires little time to complete and score.

To make the SSS-8 available in Japan, we translated the English version into Japanese and conducted a linguistic validation of the scale [14]. To ensure conceptual equivalence between the original and its translation, the translation and linguistic validation were conducted as follows: (i) forward-translation by two independent Japanese translators; (ii) back translation by a native English speaker; and (iii) pilot testing for comprehension in five patients with a history of musculoskeletal pain and somatic symptoms. Through a step-by-step process, a linguistically validated Japanese version of the SSS-8 was successfully developed, yet its psychometric properties have not been assessed.

Thus, the objective of the present study was to psychometrically validate the Japanese version of the SSS-8 for assessment of somatic symptoms in Japanese individuals.

2. Methods

2.1. Study population

Members of the Japanese general population aged 20–64 years were included in the analysis. Participants were recruited by an Internet research company, United Inc. (Tokyo, Japan), with which >1.37 million individuals across Japan have voluntarily registered. Out of approximately 1.25 million individuals aged 20–64 years selected as eligible participants, 270,000 individuals were randomly selected and invited by e-mail to complete an online questionnaire.

Participation in the online surveys was voluntary and no personally identifiable information (e.g., name and address) was collected. All participants gave their consent and were compensated. After obtaining ethical approval from The University of Tokyo, the questionnaire administration was conducted in February 2015.

2.2. Measures

The administered questionnaire included questions on demographic and clinical characteristics, the SSS-8, the EuroQol 5 Dimension (EQ-5D) [15], the brief form of the Profile of Mood States (POMS) [16,17], the Patient Health Questionnaire-2 (PHQ-2) [18], and questions on perceived stress, subjective health, and perceived general health.

The EQ-5D is an instrument developed to measure general health status [15]. It contains five questions assessing mobility, self-care, usual activities, pain/discomfort, and anxiety/depression [19]. All responses are converted into a single index score of general health status ranging from −0.11 to 1.00: a score of 1 indicates “perfect health” and a score of 0 indicates “death.” The Japanese version of the EQ-5D, which was approved by the EuroQol Group in 1997, has been widely used in research [20].

The POMS is a 65-item questionnaire that assesses the mood of individuals based on the following six mood construct domains: tension/anxiety, depression/dejection, anger/hostility, vigor, fatigue, and confusion. The present study used the POMS-Brief form, which consists of 30 items assessing the same six domains. Each item is rated on a five-point scale, and each domain score ranges from 0 to 20, with higher scores indicating more disturbances, except for the vigor domain. A Japanese version of the POMS-Brief form was shown to be reliable and valid [21].

The PHQ-2 is a questionnaire comprising two questions extracted from the universally used original Patient Health Questionnaire-9 [18]. The questions assess whether the respondent has experienced depression and anhedonia over the past 2 weeks. Although each item is rated on a scale of 0–3 in the original PHQ-2, the present study used the National Center of Neurology and Psychiatry version of the Japanese PHQ-2, which gives each item a binary response of yes or no [22]. Individuals who answer yes to at least one question are suspected of experiencing depression and a closer assessment of the individual is recommended.

Participants' perceived stress and subjective pain (including numbness) during the past 4 weeks were rated using a numerical rating scale (NRS) ranging from 0 to 10, with higher scores indicating greater stress/pain (numbness). Participants' current perceived health was also rated using an NRS on a scale of 0 to 10; a score of 0 indicates the worst health status and a score of 10 indicates the best health status.

2.3. Statistical analysis

Participants' demographic and clinical characteristics were analyzed descriptively. For descriptive statistics of the Japanese SSS-8, the total score and individual item scores were calculated to examine missing data and floor and ceiling effects (>60%).

To assess the psychometric properties of the Japanese version of the SSS-8, we evaluated its reliability and validity. Internal consistency was assessed to evaluate the reliability of the SSS-8. The extent to which items in the SSS-8 correlated with each other was evaluated using Cronbach's alpha coefficient. A Cronbach's alpha coefficient was computed for both total and symptom domain scores. A Cronbach's alpha of 0.7 or higher would indicate that the SSS-8 is internally consistent [23].

The validity was evaluated by assessing concurrent validity, known-group validity, and convergent and discriminant validity. Concurrent validity was assessed by examining associations between the SSS-8 and external reference questionnaires (EQ-5D and POMS) using Spearman's correlation coefficient. Scales that measure similar concepts should be strongly correlated; those measuring different concepts should be weakly correlated. The correlation coefficient was interpreted according to Cohen's criteria: 0.1 is considered a weak correlation; 0.3, moderate; and 0.5, strong [24].

For known-group validity, scores among different groups of participants based on the results of the PHQ-2 were examined. It was hypothesized that participant groups with more affirmative responses would have higher SSS-8 scores. To test whether there was such a linear trend across groups with different levels of depression, the Jonckheere-Terpstra test was performed [25,26]. The Jonckheere-Terpstra test is a non-parametric test, which tests if the SSS-8 scores increase as the number of affirmative response in the PHQ-2 increases, based on a hypothesis that the response distribution does not differ by the number of affirmative response.

Convergent and discriminant validity examined whether an individual item fits in its own domain (convergent validity) while the individual item does not fit in the other domains aside from its own domain (divergent validity). To assess convergent and divergent validity, the correlations between items and the symptom domains that those items assess (gastrointestinal, pain, cardiopulmonary, and fatigue domains) were calculated. It was hypothesized that items would strongly correlate with other items assumed to belong to the same symptom domain, and would weakly correlate with items assumed to belong to different symptom domains. The item-total correlations were evaluated using Spearman's correlation coefficient.

Additionally, we assessed the relationships between the Japanese SSS-8 severity groups and the participants' clinical status. Based on the SSS-8 total score, participants were categorized into five severity groups using the German version of the severity thresholds: a score of 0–3 was categorized as “no to minimal severity,” 4–7 as “low,” 8–11 as “medium,” 12–15 as “high,” and ≥16 as “very high” [5]. Among these five severity groups, all pairwise comparisons were conducted by the Steel-Dwass non-parametric test [27,28] to identify any pairs with statistically significant differences in perceived stress, subjective pain, and perceived general health.

All statistical tests were two-sided with a significance level of 0.05. Unanswered questionnaire items were treated as missing data. All analyses were performed using SAS software version 9.3 (SAS Institute, Inc., Cary, NC, USA).

3. Results

Data from 52,353 individuals who responded to the questionnaires were analyzed. Participants' demographic and clinical characteristics are summarized in Table 1. The median age was 43 years with a range of 20 to 64 years, and 50.0% of the participants were male. Median perceived stress, subjective pain, and perceived general health scores were 4 (3–6), 2 (1–4), and 6 (5–8), respectively.

Table 2 summarizes descriptive statistics of the Japanese SSS-8. To complete the questionnaire, respondents must answer all SSS-8 items; therefore, there was no missing data. No remarkable floor or ceiling effects were observed for the total scores. No ceiling effects were observed for the individual item scores; however, floor effects were observed for the following six items: stomach or bowel problems; pain in the arms, legs, or joints; headaches; chest pain or shortness of breath, dizziness; and trouble sleeping.

For reliability, internal consistency of the Japanese SSS-8 was evaluated using Cronbach's alpha coefficients. The Cronbach's alpha for the total score was 0.86, which demonstrates good consistency. The Cronbach's alpha coefficients within each symptom domain were 0.69 for the pain domain, 0.77 for the cardiopulmonary domain, and 0.77 for the fatigue domain.

To assess concurrent validity, Spearman's correlation coefficients for the associations between the SSS-8 and the two external criteria (EQ-5D, POMS) were calculated. A strong correlation was observed with the EQ-5D ($\rho = -0.54$), and also with the three POMS domains: 0.61 for the POMS-fatigue, 0.55 for the POMS-tension/anxiety, and 0.51 for the POMS-depression/dejection ($p < 0.001$ for all). For the remaining POMS domains, moderate to weak correlations were observed with the POMS-anger/hostility ($\rho = 0.46$), POMS-confusion ($\rho = 0.46$), and POMS-vigor domains ($\rho = -0.01$) ($p < 0.001$ for all).

To examine known-group validity, SSS-8 total scores were compared among groups categorized based on their responses to the PHQ-2 items: 71.6% of patients made no affirmative responses, 14.9% made one affirmative response, and 13.6% made two affirmative responses. As hypothesized, the median SSS-8 total scores and its interquartile ranges (25th–75th percentile) were higher in the groups with more affirmative responses to the PHQ-2 items: 2 (0–5) in the group with no affirmative responses, 5 (2–9) in the group with one affirmative response, and 8 (4–12) in the group with two affirmative responses. The statistical test results showed a linear increasing trend in the SSS-8 total score across these three PHQ-2 categories (which indicate suspected depression levels) (Jonckheere-Terpstra test, $p < 0.001$).

To test convergent and discriminant validity, item-total correlations were examined. Table 3 shows the Spearman's correlation coefficients between each SSS-8 item and other items belonging to the same or different symptom domains (gastrointestinal, pain, cardiopulmonary, or fatigue domains). Shaded cells in Table 3 indicate correlations between each item and the other items in the same symptom domain. Boldface text indicates each item's highest correlation, to show the domain with which it was most strongly associated. All the items except for headaches (item 4) showed the highest correlation with items within their own domain, and most of them demonstrated strong correlations ($\rho \geq 0.5$) ($p < 0.001$ for all correlations). Item 4 showed the highest correlation with the cardiopulmonary domain ($\rho = 0.48$) instead of with its own pain domain ($\rho = 0.38$).

The plausibility of the Japanese SSS-8 severity groups based on the SSS-8 total score was examined by comparing the median scores on perceived stress, subjective pain, and perceived general health in each severity group (Table 4). For both perceived stress and subjective pain, median NRS scores were higher for more severe category groups, and the score differences between any pair of severity groups were significant (Steel-Dwass test, $p < 0.001$). For perceived general health, median scores were lower for more severe category groups. As with the stress and pain scores, this indicates that participants in more severe groups experience greater symptom burden. The score differences were significant between all pairs of severity groups (Steel-Dwass test, $p < 0.001$) except for between the "high" and "very high" groups (Steel-Dwass test, $p = 0.13$).

Table 1
Participants' demographic and clinical characteristics ($n = 52353$).

Characteristics	
Age, years (median, range)	43 (20–64)
Sex, male (n, %)	26,191 (50.0)
Educational qualification (n, %)	
Junior high school	1293 (2.5)
High school	16,105 (30.8)
Vocational school	7105 (13.6)
Technical college	855 (1.6)
Junior college	5302 (10.1)
University	19,102 (36.5)
Graduate school	2191 (4.2)
Others	400 (0.8)
Employment status (n, %)	
Full-time employee	20,565 (39.3)
Part-time/contract employee	9945 (19.0)
Temporary staff	1783 (3.4)
Business executive	2903 (5.6)
Family business	765 (1.5)
Work at home	1267 (2.4)
Students	1861 (3.6)
Do housework	7843 (15.0)
Without job	4363 (8.3)
Others	1058 (2.0)
Perceived stress (NRS) (median, IQR)	4 (3–6)
Subjective pain (NRS) (median, IQR)	2 (1–4)
Perceived general health (NRS) (median, IQR)	6 (5–8)

Values are median (range), n (%), or median (IQR). IQR = interquartile range (25th–75th percentile); NRS = numerical rating scale (score range: 0 to 10).

4. Discussion

This study used data collected online from 52,353 individuals to assess the psychometric properties of the Japanese SSS-8, which had been linguistically validated previously. Overall, the results demonstrated that the Japanese SSS-8 had good internal consistency, and acceptable to good concurrent validity, known-group validity, and convergent and discriminant validities.

Although the descriptive statistics of the Japanese SSS-8 revealed no ceiling or floor effects for the Japanese SSS-8 total scores, a floor effect was observed for six individual items. This is probably because the present study sampled members of the Japanese general population, who did not necessarily have any somatic symptoms, and because item scores were between 0 and 4. In fact, over 50% of the participants obtained total scores of between 0 and 5. Therefore, these floor effects were not considered critical.

The internal consistency of the Japanese SSS-8 was evaluated here using Cronbach's alpha coefficient [29]. The coefficient exceeded a generally acceptable level of 0.7 for psychometric scales and reached over 0.8, which is regarded as a good level. These levels are similar to the Cronbach's alpha of 0.81 found for the German SSS-8 [5].

The validity of the Japanese SSS-8 was evaluated by examining concurrent validity, known-group validity, and convergent and discriminant validity. The concurrent validity analysis showed strong correlations exceeding 0.5 (or -0.5) between the Japanese SSS-8 and the measures of self-reported health status, fatigue, anxiety, and depression. Known-group validity was also found: there was a statistically significant trend for patients with more depression symptoms to report higher Japanese SSS-8 scores. Both the concurrent validity and known-group validity results found here indicate relationships between

Table 2
SSS-8 total scores and distributions of individual item scores.

	Mean	SD	Median	Range Min–Max	Floor effect (%)	Ceiling effect (%)
Total score	4.5	5.2	3	0–32	24.9	0.4
1. Stomach or bowel problems	1.6	0.9	1	1–5	64.4	1.5
2. Back pain	1.8	1.0	1	1–5	53.6	2.7
3. Pain in the arms, legs, or joints	1.5	0.9	1	1–5	67.0	1.9
4. Headaches	1.6	0.9	1	1–5	66.6	2.0
5. Chest pain or shortness of breath	1.3	0.7	1	1–5	83.9	1.1
6. Dizziness	1.3	0.7	1	1–5	81.0	1.3
7. Feeling tired or having low energy	1.9	1.1	1	1–5	50.1	3.9
8. Trouble sleeping	1.6	1.0	1	1–5	67.4	3.0

SSS-8 = Somatic Symptom Scale-8; SD = standard deviation; Min = minimum; Max = maximum.

somatic burden, anxiety, and depression, which supports previous research showing that somatic, anxiety, and depression symptoms are highly comorbid and partially overlap [30,31].

For the convergent and discriminant validities, the highest correlations were between each question item and the domain to which it belonged, with the exception of the headaches item. Headaches had the highest correlation with the cardiopulmonary domain (0.48), followed by the fatigue domain (0.45). Although headaches are a type of pain, they differ from back pain and pain in your arms, legs, or joints which are classified as musculoskeletal pain. Earlier research grouped headache into the category of general symptoms or head-and-gastrointestinal symptoms along with symptoms such as dizziness and fatigue as a result of factor analysis in somatic symptoms [32–34]. In fact, when looking into correlation between each items rather domains, headaches in the present study indicated the highest correlation with dizziness ($\rho = 0.45$) followed by feeling tired or having low energy ($\rho = 0.44$). Therefore, headaches showing such stronger correlations with the cardiopulmonary and fatigue domains may be accountable. Similarly in the German version of the SSS-8, confirmatory factor analysis results revealed coefficients of between 0.61 and 0.84; the lowest was for headaches and the highest for pain in the arms, legs, or joints in the pain domain [5]. This may have resulted from differences in sampling methods; however, the observed lowest coefficient for headaches in the present study is consistent with the German findings.

Furthermore, five severity thresholds from the German SSS-8 are applicable to the Japanese general population. For the German version of the SSS-8, the severity increased as levels of perceived stress, pain, and general health increased [5]. The differences between all pairs were statistically significant, except for the pair of high and very high in perceived general health. However, as the medians in high and very high were the same for perceived stress and general health, further research is warranted to determine whether the category cutoff points for high and very high are appropriate for the Japanese general population.

There are several limitations of the present study. First, generalization of these results is limited. As recruitment was conducted online, some demographic groups may have been under-represented (e.g., those without access to the Internet) and some over-represented (e.g., those with a greater motivation to participate). In addition, the recruitment targets were limited to registered individuals between the ages of 20 and 64 years (considered to be the working age population). However, the present study obtained a large sample from the general Japanese population and this sample reflected the age and sex composition ratio of the Japanese population. Therefore, such under- or over-represented groups may not be a critical problem in the present study. Second, misclassifications of response and recall bias are concerns. Response misclassification is inevitable when using subjective measures. Recall bias toward retrospective questions might also have distorted participants' responses. Therefore, these need to be interpreted with caution. Third, the present study did not evaluate the responsiveness of the Japanese SSS-8. The ability of the questionnaire to detect changes if the condition changes (e.g., responsiveness to treatment) needs to be evaluated prior to its use in longitudinal studies. Further assessment of responsiveness is thus necessary. Fourth, as the present study targeted the general population residing in Japan, use of the Japanese SSS-8 in a clinical setting may produce results that differ from the present results. The English version of the SSS-8, a short form of the PHQ-15 [4], was originally developed for the DSM-5 field trials [12], and its German version has been psychometrically validated for the German general population, suggesting that the SSS-8 could be applicable to both clinical and general populations [5]. However, the relevance of the Japanese SSS-8 for patients in Japan needs to be demonstrated.

Table 3
Correlations[a] among each item and other items belonging to the same or different symptom domains.

	Domain			
SSS-8 Item	Gastrointestinal Item #1	Pain Item #2–4	Cardiopulmonary Item #5–6	Fatigue Item #7–8
1. Stomach or bowel problems	**1.00**	0.46	0.41	0.45
2. Back pain	0.39	**0.51**	0.38	0.44
3. Pain in your arms, legs, or joints	0.32	**0.47**	0.38	0.38
4. Headaches	0.39	0.38	**0.48**	0.45
5. Chest pain or shortness of breath	0.38	0.43	**0.50**	0.43
6. Dizziness	0.36	0.43	**0.50**	0.44
7. Feeling tired or having low energy	0.43	0.52	0.47	**0.57**
8. Trouble sleeping	0.38	0.43	0.43	**0.57**

[a]Spearman's correlation coefficient.

SSS-8 = Somatic Symptom Scale-8. Item 1 comprises thegastrointestinal symptoms domain, items 2–4 comprise the pain domain, items 5–6 comprise the cardiopulmonary domain, and items 7–8 comprise the fatigue domain. All the correlations were p <0.001.

Table 4
Stress, pain, and overall health NRS scores for each SSS-8 severity category.

SSS-8 severity category (SSS-8 score)	n (%)	Perceived stress (NRS) Median (IQR)	Subjective pain (NRS) Median (IQR)	Perceived general health (NRS) Median (IQR)
No to minimal (0–3)	29,294 (56.0)	3 (2–5)	1 (0–3)	7 (5–8)
Low (4–7)	12,243 (23.4)	5 (3–7)	3 (2–5)	6 (4–7)
Medium (8–11)	5731 (10.9)	6 (4–7)	4 (3–6)	5 (4–6)
High (12–15)	2725 (5.2)	7 (5–8)	5 (3–7)	4 (3–6)
Very high (≥16)	2360 (4.5)	7 (5–8)	6 (4–7)	4 (3–6)

Score differences between severity groups were tested ($p < 0.001$ for all pairs of severity groups in perceived stress and subjective pain and $p < 0.001$ for all pairs in perceived general health, except for a pair of high and very high groups, $p = 0.13$).
SSS-8 = Somatic Symptom Scale-8; NRS = numerical rating scale; IQR = interquartile range (25th–75th percentile).

In sum, the present study demonstrated that our linguistically validated version of the Japanese SSS-8 was valid with a good internal consistency. Our results also suggested that the somatic symptom burdens determined by the SSS-8 severity thresholds were in proportion to individuals' perceptions of stress and pain levels and inverse to their perception of health status. This brief questionnaire could be useful in a medical setting and could help to detect the somatic symptom burden of chronic and severe musculoskeletal pain for primary prevention.

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ORIGINAL RESEARCH

The relationship between findings on magnetic resonance imaging and previous history of low back pain

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Abstract: The objective of this study was to evaluate the relationship between magnetic resonance imaging (MRI) findings and previous low back pain (LBP) in participants without current LBP. Current LBP was defined as LBP during the past month. Previous LBP was defined as a history of medical consultation for LBP. Ninety-one participants without current LBP were included. Sagittal T2-weighted MRI was used to assess the intervertebral space from T12/L1 to L5/S1. These images were classified into five grades based on the Pfirrmann grading system. Furthermore, we evaluated the presence of disk bulging, high-intensity zone, and spondylolisthesis. We compared the MRI findings between groups with (27 participants) and without (64 participants) previous LBP without current LBP. Intraobserver and interobserver kappa values were evaluated. Participants had an average age of 34.9 years; 47 were female and 44 were male; and their average body mass index was 21.8 kg/m^2. Compared to the group of participants without previous LBP, the group of participants with previous LBP had a significantly higher incidence of disk degeneration such as a Pfirrmann grade ≥3, disk bulging, and high-intensity zone in the analyses adjusted by age and sex. There were no significant differences in spondylolisthesis between the groups. An odds ratio of >10 was only found for Pfirrmann grade ≥3, ie, a Pfirrmann grade ≥3 was strongly associated with a history of previous LBP in participants without current LBP.

Keywords: disk bulging, low back pain, magnetic resonance imaging, MRI, Pfirrmann grading, previous history, high-intensity zone

Introduction

Low back pain (LBP) affects most adults at some point in their lives. Approximately 85%–90% of cases are classified as nonspecific LBP.[1] In the last decade, LBP was continuously found to be the top leading cause of years lived with disability globally.[2] Similarly, in Japan, LBP is one of the most common causes of health disability, as in other industrialized countries, with a reported lifetime prevalence of >80%.[3] Especially in the workplace, LBP is an important and costly medical problem that leads to decreased employee health and productivity.[4]

Magnetic resonance imaging (MRI) can identify underlying pathologies of LBP. However, the importance of MRI findings is unclear and controversial. Some reports have shown that disk degeneration was associated with LBP,[5–7] while others have shown that there was no relationship between disk degeneration and LBP.[8,9] Although these reports focused on the relationship between disk degeneration and current LBP, there are a few reports on the relationship between MRI findings, including disk degeneration

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and previous LBP.[5,10] It has been suggested that symptoms of chronic LBP are often fluctuating, and this is a condition with a pattern of exacerbation and remission.[11] Some individuals have chronic LBP, whereas others have intermittent pain. We anticipate that if physicians know about the predictive MRI findings of recurrent severe LBP, we can selectively educate patients about preventing LBP. Therefore, we hypothesized that people whose lumbar MRI showed disk degeneration would be prone to developing severe LBP, unless they did not have current severe LBP. The purpose of this study was to evaluate the relationship between MRI findings and previous LBP symptoms in participants without current LBP.

Materials and methods

Study participants

From September 2005 to March 2006, we recruited volunteers who were personnel at Kanto Rosai Hospital to participate in the study. Ninety-one participants without current LBP were included. We administered a questionnaire to determine whether they had previous LBP symptoms. According to previous reports, current LBP was defined as pain localized between the costal margin and the inferior gluteal folds depicted in a diagram with or without lower extremity pain in the past 1 month.[1,12] The area was shown diagrammatically on the questionnaire according to a previous study.[12] Previous LBP was defined as a history of medical consultation for LBP. Medical consultation for LBP is one of the standards for evaluating the severity of LBP.[13] This indicated that the LBP was not mild. Then, we classified the participants into two groups, those with previous LBP and those without previous LBP. The study was approved by the review board of the Minister of Labor, Health, and Welfare of Japan. Written informed consent was obtained from all individual participants included in the study.

Image assessment

MRI was performed using a 1.5 T Siemens Symphony scanner (Siemens Healthcare, Erlangen, Germany). The imaging protocol included sagittal T2-weighted fast spin echo (repetition time: 3,500 ms/echo, echo time: 120 ms, and field of view: 300 × 320 mm). Sagittal T2-weighted images were used to assess the intervertebral space from T12/L1 to L5/S1. Assessment of the MRI scans was performed by an orthopedist (J.T.) who was blinded to the participants' backgrounds. We evaluated the degree of disk degeneration, disk bulging, the high-intensity zone (HIZ), and spondylolisthesis at each level of the spine. The degree of disk degeneration on MRI was classified into five grades based on the Pfirrmann classification system.[14] In the analysis, we divided Pfirrmann grading into two categories, grades 1–2 and grades 3–5. Disk bulging was defined as displacement of the disk material, usually by >50% of the disk circumference and <3 mm beyond the edges of the disk space in the axial plane.[15] As we were only able to evaluate the sagittal planes of MRI scans, we defined disk bulging as posterior disk displacement <3 mm and equivalent to the anterior disk displacement in the sagittal plane. We defined HIZ as an area of brightness or high signal intensity located in the posterior annulus on T2-weighted images based on previous literature.[16] We defined spondylolisthesis as vertebral slips of >5 mm. To evaluate intraobserver variability, 20 randomly selected MRI scans of the lumbar spine were rescored by the same observer (J.T.) >1 month after the first reading. Furthermore, to evaluate interobserver variability, 20 other MRI scans were scored by two orthopedists (J.T. and A.H.) using the same classification.

Finally, we focused on comparing the relationship between the MRI findings and previous LBP.

Statistical analysis

The kappa statistic was used to summarize the intrareader and interreader reliability of the ratings. The kappa statistics were calculated with linear weights to give less importance to disagreements closer together on an ordinal scale. The schema of Landis and Koch[17] was used to interpret the strength of agreement based on the following values: 0, poor; 0–0.20, slight; 0.21–0.40, fair; 0.41–0.60, moderate; 0.61–0.80, substantial; and 0.81–1.00, almost perfect. Between-group differences in baseline characteristics were evaluated using the Fisher's exact test for categorical variables and the Student's *t*-test for continuous variables. We compared the MRI findings between groups with and without previous LBP that did not have current LBP by using the Fisher's exact test. Furthermore, we determined the odds ratios of each item using univariate analyses and adjusting the analyses by age and sex. The statistical analyses were performed using the JMP 11.0 software program (SAS Institute, Cary, NC, USA). A p-value of <0.05 was considered to be significant.

Results

Of 91 participants, 27 had a history of LBP, which was indicated during medical consultation. The remaining 64 participants did not have any history of LBP. Participants' average age was 34.9 ± 10.6 years; 47 were female and 44 were male; and their average body mass index (BMI) was 21.8 ± 3.0 kg/m^2. The average ages of those who did and did

Table 1 Demographic data of the participants

Backgrounds	Total, n = 91	Previous LBP (+) group, n = 27	Previous LBP (–) group, n = 64	*p*-value
Age (years)	34.9 ± 10.6	38.3 ± 10.7	33.5 ± 10.4	0.0486*
Sex				
Female	47	12 (25.5)	35 (74.5)	0.3718
Male	44	15 (34.1)	29 (65.9)	
BMI (kg/m^2)	21.8 ± 3.0	21.8 ± 0.6	21.7 ± 0.4	0.9639

Notes: Data are shown as mean ± standard deviation or the number of participants (%). *$p < 0.05$.
Abbreviations: –, negative; +, positive; LBP, low back pain; BMI, body mass index.

Table 2 Details of the intraobserver and interobserver reliability of Pfirrmann grading, disk bulging, the high-intensity zone, and spondylolisthesis on magnetic resonance imaging reading

MRI findings	MRI (n)	Kappa	95% CI
Pfirrmann grading			
Intraobserver reliability	20 vs 20	0.66	0.55–0.77
Interobserver reliability	20 vs 20	0.64	0.52–0.76
Disk bulging			
Intraobserver reliability	20 vs 20	0.60	0.39–0.81
Interobserver reliability	20 vs 20	0.67	0.48–0.87
High-intensity zone			
Intraobserver reliability	20 vs 20	0.85	0.64–1.06
Interobserver reliability	20 vs 20	0.93	0.79–1.07
Spondylolisthesis			
Intraobserver reliability	20 vs 20	NA	NA
Interobserver reliability	20 vs 20	NA	NA

Abbreviations: CI, confidence interval; MRI, magnetic resonance imaging; NA, not applicable.

not have a history of LBP were 38.3 and 33.5 years, respectively, which were significantly different ($p = 0.0486$). There were no significant differences in sex and BMI between the groups (Table 1).

The intraobserver and interobserver variabilities for Pfirrmann grading on MRI were 0.66 and 0.64, respectively. Those for disk bulging were 0.60 and 0.67, respectively. Those for the HIZ were 0.85 and 0.93, respectively. In 20 randomly selected MRIs, one observer did not identify spondylolisthesis at all, while the other observer identified spondylolisthesis in two levels of one participant. Thus, the intraobserver and interobserver variabilities for spondylolisthesis could not be calculated (Table 2).

Compared to the group without previous LBP, the group with previous LBP had a significantly higher incidence of disk degeneration such as a Pfirrmann grade ≥3 in at least one spinal level ($p = 0.0026$). In addition, the group with previous LBP had a significantly higher incidence of disk bulging in at least one spinal level than the group without previous LBP ($p = 0.0019$). There were no significant differences in HIZ ($p = 0.0883$) and spondylolisthesis ($p = 0.0766$) between the two groups according to the results of the

Table 3 Magnetic resonance imaging findings at any spinal level in groups with and without previous LBP that did not have current LBP

MRI findings	Total, n = 91	Previous LBP (+) group, n = 27	Previous LBP (–) group, n = 64	*p*-value
Pfirrmann grade ≥3	69 (75.8)	26 (96.3)	43 (67.2)	0.0026*
Disk bulging +	48 (52.3)	21 (77.8)	27 (42.2)	0.0019*
High-intensity zone +	19 (20.9)	9 (33.3)	10 (15.6)	0.0883
Spondylolisthesis +	4 (4.4)	3 (11.1)	1 (1.6)	0.0766

Notes: Data are shown as the number of participants (%). *$p < 0.05$.
Abbreviations: –, negative; +, positive; LBP, low back pain; MRI, magnetic resonance imaging.

Fisher's exact test (Table 3). Regarding the findings for each spinal level, compared to the group without previous LBP, the group with previous LBP had a significantly higher incidence of disk degeneration such as a Pfirrmann grade ≥3 at the T12/L1 ($p = 0.0350$), L3/4 ($p = 0.0232$), L4/5 ($p = 0.0005$), and L5/S1 ($p = 0.0026$) levels; and disk bulging at the L2/3 ($p = 0.0277$), L3/4 ($p = 0.0113$), L4/5 ($p = 0.0018$), and L5/S1 levels ($p = 0.0081$; Table 4). The findings of HIZ were almost all observed at the L4/5 and L5/S1 levels. Spondylolisthesis was only observed at the L4/5 and L5/S1 levels. In univariate analyses, the odds ratios of a Pfirrmann grade ≥3, disk bulging, HIZ, and spondylolisthesis were 12.7, 4.8, 2.7, and 7.9, respectively. There were significant differences for a Pfirrmann grade ≥3 ($p = 0.0009$) and disk bulging ($p = 0.0015$) in univariate analyses. In the adjusted analyses by age and sex, the odds ratios of the aforementioned four items were 10.5, 4.2, 3.1, and 6.6, respectively, and there were significant differences for a Pfirrmann grade ≥3 ($p = 0.0065$), disk bulging ($p = 0.0047$), and HIZ ($p = 0.0405$; Table 5).

Discussion

Among the participants in this study, ~30% had previous LBP, which was determined during the medical consultation. As in many industrialized countries, LBP is one of the most common health disabilities in Japan. In a population-based

Table 4 Pfirrmann grade and disk bulging at each spinal level in groups with and without previous LBP that did not have current LBP

MRI findings	Level	Total, n = 91	Previous LBP (+) group, n = 27	Previous LBP (–) group, n = 64	*p*-value
Pfirrmann grade ≥3	T12/L1	18 (19.8)	9 (33.3)	9 (14.1)	0.0350*
	L1/2	22 (24.2)	9 (33.3)	13 (20.3)	0.1851
	L2/3	30 (33.0)	10 (37.0)	20 (31.3)	0.5917
	L3/4	44 (48.4)	18 (66.7)	26 (40.6)	0.0232*
	L4/5	56 (61.5)	24 (88.9)	32 (50.0)	0.0005*
	L5/S1	56 (61.5)	23 (85.2)	33 (51.6)	0.0026*
Disk bulging (+)	T12/L1	2 (2.2)	1 (3.7)	1 (1.6)	0.5245
	L1/2	1 (1.1)	1 (3.7)	0 (0.0)	0.1216
	L2/3	2 (2.2)	2 (7.4)	0 (0.0)	0.0277*
	L3/4	5 (5.5)	4 (14.8)	1 (1.6)	0.0113*
	L4/5	35 (38.5)	17 (63.0)	18 (28.1)	0.0018*
	L5/S1	35 (38.5)	16 (59.3)	19 (29.7)	0.0081*

Notes: Data are shown as the number of participants (%). $*p < 0.05$.
Abbreviations: –, negative; +, positive; LBP, low back pain; MRI, magnetic resonance imaging.

Table 5 Odds ratio, 95% CI, and *p*-value from univariate analyses and analyses adjusted by age and sex for magnetic resonance imaging findings of groups with and without previous LBP that did not have current LBP

MRI findings	Univariate analyses			Age-adjusted and sex-adjusted analyses		
	Odds ratio	95% CI	*p*-value	Odds ratio	95% CI	*p*-value
Pfirrmann grade ≥3	12.7	2.43–234.18	0.0009*	10.5	1.78–202.09	0.0065*
Disk bulging	4.8	1.79–14.55	0.0015*	4.2	1.54–13.15	0.0047*
High-intensity zone	2.7	0.94–7.78	0.0652	3.1	1.05–9.42	0.0405*
Spondylolisthesis	7.9	0.96–163.50	0.0551	6.6	0.74–141.71	0.0923

Note: $*p < 0.05$.
Abbreviations: CI, confidence interval; LBP, low back pain; MRI, magnetic resonance imaging.

survey, the lifetime and 4-week LBP prevalence was 83% and 36%, respectively.[3] Therefore, LBP is one of the common causes of disability. In the current study, we precisely defined the region of LBP, which seemed to be important for standardizing the study protocol for LBP.[1,12] We also defined previous LBP as a history of medical consultation for LBP, which can exclude mild previous LBP. There was a significant difference in age between the two groups. Considering that disk degeneration progresses with advancing age,[6] the analyses performed in our study can be considered as appropriate.

The intraobserver and interobserver variabilities for each MRI finding were greater than moderate for all evaluated items.

MRI findings consistent with Pfirrmann grade ≥3, especially at the lower lumbar disk level, disk bulging, and HIZ were associated with previous LBP. Spondylolisthesis was not associated with previous LBP. There were significant differences between the groups in terms of a Pfirrmann grade ≥3, disk bulging, and HIZ according to the analyses adjusted by age and sex. The odds ratio of only the Pfirrmann grade ≥3 was >10, ie, a Pfirrmann grade ≥3 is strongly associated with a history of previous LBP in those without current LBP.

Pfirrmann grading indicates the degree of disk degeneration.[14] We divided the grading into two groups for the purpose of analysis. We regarded those with grades 1–2 as having no or little disk degeneration and those with grades 3–5 as having some degree of disk degeneration. There have been many reports on the relationship between current LBP and disk degeneration;[5–7] however, none have reported on the relationship between previous LBP and Pfirrmann grading. Videman et al[10] showed that disk height narrowing was associated with previous LBP, but they did not use Pfirrmann grading. Since disk height narrowing was classified as Pfirrmann grade 5,[14] this can be interpreted as implying that severe disk degeneration was associated with previous LBP. Although we included Pfirrmann grades 5, 3, and 4, which did not indicate severe disk height narrowing, our findings were almost consistent with the previous study's findings in terms of disk degeneration.

Pfirrmann grade ≥3 at T12/L1, L3/4, L4/5, and L5/S1 was associated with previous LBP. A large population study showed that disk degeneration was most commonly affected at L5-S1 and L4-L5,[6] which corresponds with our findings. A mechanical study showed that the range of motion in the lower lumbar segments was significantly smaller than that in the upper segments.[18] The small range of motion at the intervertebral disk space can cause the load to increase at the disk, which can easily cause disk degeneration. This may be a reason why disk degeneration was more prominent at the lower lumbar disk levels than at the upper disk levels in the current study.

Disk bulging was associated with previous LBP. Regarding each spinal level, disk bulging at the L2/3, L3/4, L4/5, and L5/S1 levels was associated with previous LBP. Although the *p*-values were inclined to be smaller at lower disk levels than at upper disk levels, previous LBP was associated with disk bulging at almost all the lumbar disk levels. Some studies have shown that disk bulging was frequently observed in asymptomatic subjects, and it was concluded that there was no relationship between disk bulging and current LBP,[19,20] whereas another study of a meta-analysis showed a strong relationship.[7] As for previous LBP, Videman et al[10] showed that disk bulging was not associated with previous LBP. Our findings were not consistent with previous findings in terms of disk bulging.

A systematic review of the relationship between MRI findings and current LBP showed that disk degeneration and disk bulging are associated with current LBP, especially in younger adults, and this relationship disappears in older populations.[7] Although the study did not mention previous LBP, we can assume that older adults with disk degeneration or disk bulging who do not have current LBP may have had LBP when they were younger. These results correspond with our findings.

The HIZ was often observed at the level of L4/5 and L5/S1, and it was associated with previous LBP. There was a significant difference in the analyses adjusted by age and sex ($p = 0.0405$), although no significant relationship was found using the Fisher's exact test and univariate analyses. Aprill and Bogduk[16] reported a strong correlation between the annular high signal intensity zone and positive provocative discography. Some study has shown that the HIZ was associated with current LBP.[21] Dongfeng et al[22] performed a histological study on excised disks with a HIZ, and they concluded that the HIZ may be a specific signal for the inflammatory reaction of a painful disk. Conversely, other studies have shown that the HIZ was frequently observed in asymptomatic subjects.[7,19,20] As for previous LBP, Videman et al[10] showed that annular tear on axial MRI scans was associated with previous LBP. However, there has been no report on the relationship between the HIZ and previous LBP.

Spondylolisthesis was considered to be one of the findings of lumbar spine instability.[23] Considering that instability of the lumbar spine can cause LBP, it was assumed that those who had spondylolisthesis were inclined to have LBP.[24] However, some reports identified no significant relationship between spondylolisthesis and current LBP.[7,25] Furthermore, Hasegawa et al[26] showed that the radiological findings of spondylolisthesis cannot indicate instability. However, there has been no report on the relationship between spondylolisthesis and previous LBP. In our study, only four participants who did not have current LBP had spondylolisthesis. Three of these had previous LBP, and only one did not have previous LBP. There was no significant relationship between spondylolisthesis and previous LBP; however, this may be attributed to the small number of spondylolisthesis cases in our study.

One systematic review showed that HIZ and spondylolisthesis are not associated with current LBP, even in younger adults.[7] Therefore, the aforementioned information about disk degeneration or disk bulging does not correspond with HIZ and spondylolisthesis.

While some chronic LBP patients show continuous pattern, others have intermittent pattern.[11] Therefore, there was a possibility that the participants in our study who had previous LBP without current LBP had chronic LBP as intermittent pain. They did not have LBP at the time of participation; however, they may suffer recurrent LBP in the future as a natural course in the intermittent LBP pattern. Based on the results of the current study, MRI findings consistent with Pfirrmann grade ≥3, disk bulging, and HIZ may be one of the predictive signs of recurrent severe LBP. Thus, we can selectively educate patients about preventing LBP.

There were some limitations to the current study. First, we did not evaluate end plate changes because we only analyzed sagittal T2-weighted images and T1-weighted images were unavailable, even though Modic change has been considered to be associated with LBP.[5] In a population-based study on 975 participants, Teraguchi et al[27] showed that the combination of disk degeneration and end plate changes was highly associated with current LBP, whereas disk degeneration alone was not associated with current LBP. There is no previous report on the relationship between end plate changes and previous LBP, and we did not assess this relationship in our study. Second, we only analyzed sagittal images. Disk bulging and the HIZ can sometimes be visible at the posterolateral sides; however, these can be underestimated. Third, there was selection bias among our study participants, as they were volunteers from all types of employment at the hospital and did not represent the general population.

Conclusion

MRI findings consistent with Pfirrmann grading ≥3, especially at the lower lumbar disk level, disk bulging, and HIZ were associated with previous LBP. In addition, spondylolisthesis was not associated with previous LBP. These findings may be one of the predictive signs of recurrent severe LBP.

Disclosure

The authors report no conflicts of interest in this work.

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Original Article

The Japanese version of the STarT Back Tool predicts 6-month clinical outcomes of low back pain

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ABSTRACT

Background: The STarT Back Tool classifies patients into low-, medium-, or high-risk groups according to risk for chronic low back pain. The Japanese version of the STarT Back Tool (STarT-J) has been translated and psychometrically validated. The present analysis investigated the predictive ability of the STarT-J.
Methods: Baseline data were collected through an online survey conducted with Japanese patients with low back pain. Long-term outcomes were assessed in a 6-month follow-up survey. Clinical outcomes at 6 months were evaluated with a pain numerical rating scale, the Roland–Morris Disability Questionnaire, and the EuroQol 5 Dimension. Differences in these scores among the three STarT-J risk groups were analyzed. Participants' perceived changes in low back pain and overall health status were examined to determine associations between the chronicity of low back pain at 6 months and STarT-J risk groups.
Results: Data of 1228 volunteers who responded to the baseline and follow-up surveys were included in this analysis. Mean ± standard deviation (SD) scores for the pain numerical rating scale and the Roland–Morris Disability Questionnaire were highest in the high-risk group (5.6 ± 1.9 and 9.6 ± 7.5) and lowest in the low-risk group (3.9 ± 1.6 and 2.1 ± 3.5). Mean ± SD EuroQol 5 Dimension index scores were lowest in the high-risk group (0.66 ± 0.20) and highest in the low-risk group (0.86 ± 0.14). A small percentage of high-risk patients (5.3%) perceived improvement in low back pain at the 6-month follow-up.
Conclusions: The STarT-J predicted 6-month pain and disability outcomes. The STarT-J is an easy-to-use tool to screen for patients who are more likely to have chronic low back pain, and may be useful to initiate stratified care in primary care settings.

1. Introduction

Stratified care to provide targeted treatment suitable for specific groups of patients has become a dominant approach in the management of low back pain (LBP) [1]. Stratification can be determined in several ways (e.g., based on underlying causes, prognostic factors, and patients' responses to treatment), but stratification based on prognostic factors is a prominent approach in primary care [1]. Evidence-based guidelines recommend that prognostic factors should be identified in deciding the management of LBP [2,3].

In assessing prognostic factors, early identification of risk for persistent LBP is particularly important [4], as recovery from chronic LBP is less likely when pain and disability are prolonged [5]. It is widely recognized that psychological factors such as depression, pain catastrophizing, and fear-avoidance beliefs contribute to the chronicity of LBP [6]. Therefore, it is especially important to screen for the presence of psychological factors in the early stages of LBP, to help predict the risk for chronicity and determine the most appropriate future management strategy.

The STarT Back Tool (STarT) is a multidimensional screening measure that identifies risk for chronic LBP by assessing physical and psychological prognostic factors [7]. The STarT classifies patients into three risk groups based on scores on nine overall items and five psychosocial subscale items (items 5–9) (Fig. 1) [8].

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Patients with a total score of 0–3 are classified as low-risk, those with a total score of ≥4 but a psychosocial subscore of ≤3 are medium-risk, and those with a psychosocial subscore of ≥4 are classified as high-risk. Providing education and support for self-management may be suitable for low-risk patients, and physical therapy may reduce pain and disability for medium-risk patients. For patients in the high-risk group, a combination of cognitive-behavioral therapy and physical therapy would be appropriate to manage psychological obstacles [9]. Stratified care based on the STarT risk classification has been demonstrated to be clinically and economically beneficial for patients with LBP [9,10]. Because of its benefits and usefulness, the STarT has been translated into various languages and is used worldwide [11–18].

In Japan, Matsudaira et al. translated and linguistically validated the Japanese version of the STarT (STarT-J) [19], and assessed its psychometric properties using cross-sectional data [20]. For concurrent validity, an overall moderate correlation was found between the STarT-J and external reference questionnaires. Known-groups validity was demonstrated by assessing the relationships between the STarT-J total scores or risk groups and the LBP-associated disability. The Cronbach's alpha coefficient showed the overall scale of the STarT-J had good internal consistency. The analysis demonstrated that the STarT-J was valid and reliable for the assessment of LBP in the Japanese population [20]. However, clinical outcomes of patients who were classified using the STarT-J have not yet been investigated.

Therefore, the present analysis assessed the relationships between the STarT-J risk groups and clinical outcomes for the stratified patients with LBP. We used longitudinal data to investigate whether the STarT-J high-risk group would have more chronic LBP at a 6-month follow-up.

2. Materials and methods

2.1. Study population

The present analysis is a part of a larger study consisting of a series of online surveys on LBP in the Japanese population. The baseline survey was conducted in January to February 2014, to investigate the physical and psychological aspects of patients with LBP. Participants were volunteers who were aged 20–64 years and recently had LBP, recruited through an online panel provided by an Internet research company, UNITED, Inc. (Tokyo, Japan). According to the standard definition of LBP by Dionne et al. [21], LBP was defined as pain in the low back that was experienced in the last 4 weeks and that lasted for more than 1 day. Pain associated with menstruation or pregnancy and pain during a feverish illness were excluded. Responses were obtained from 2000 individuals. To assess long-term clinical outcomes, a follow-up survey was conducted 6 months later and responses were received from 1228 individuals. In the present analysis, we used data of these 1228 participants for whom baseline and follow-up survey data were

The Keele STarT Back Screening Tool

Patient name: ______________________________ Date: _____________

Thinking about the **last 2 weeks** tick your response to the following questions:

		Disagree 0	Agree 1
1	My back pain has **spread down my leg(s)** at some time in the last 2 weeks	☐	☐
2	I have had pain in the **shoulder** or **neck** at some time in the last 2 weeks	☐	☐
3	I have only **walked short distances** because of my back pain	☐	☐
4	In the last 2 weeks, I have **dressed more slowly** than usual because of back pain	☐	☐
5	It's not really safe for a person with a condition like mine to be physically active	☐	☐
6	**Worrying thoughts** have been going through my mind a lot of the time	☐	☐
7	I feel that **my back pain is terrible** and **it's never going to get any better**	☐	☐
8	In general I have **not enjoyed** all the things I used to enjoy	☐	☐

9. Overall, how **bothersome** has your back pain been in the **last 2 weeks**?

Not at all	Slightly	Moderately	Very much	Extremely
☐	☐	☐	☐	☐
0	0	0	1	1

Total score (all 9): _________________ **Sub Score (Q5-9):**_____________

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Fig. 1. The STarT Back Tool. Items 5–9 constitute the psychosocial subscale.

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available, and investigated the 6-month clinical status of participants in each STarT-J risk group. A 6-month follow-up period was chosen because the predictive validity of the original STarT developed in UK was tested using 6-month follow-up data [8].

The present analysis received approval from the medical/ethics review board of the Japan Labour Health and Welfare Organization, Kanto Rosai Hospital. Participation was voluntary, and no personal information was collected. Because of the nature of the study (online surveys), no written informed consent was obtained. As potential participants first read an explanation of the aim of the survey and only those who were willing to participate could proceed to the questionnaire, submission of a completed questionnaire was considered as evidence of consent. As an incentive, reward points for online shopping were given to the survey respondents from the Internet research company.

2.2. Measures

The following measures were included in the 6-month follow-up survey to assess participants' long-term clinical outcomes.

2.2.1. Numerical rating scale (NRS)

A NRS was used to assess the degree of pain related to LBP. The scale ranged from 0 (no pain at all) to 10 (the worst pain imaginable).

2.2.2. The Roland–Morris Disability Questionnaire (RDQ)

The RDQ was used to assess LBP-associated disability participants experienced in their daily lives. The RDQ consists of 24 Yes/No questions, and the total score ranges from 0 to 24. A higher score indicates greater disability. The validity and reliability of the Japanese version of the RDQ have been previously confirmed [22].

2.2.3. The EuroQol 5 Dimension (EQ-5D)

The EQ-5D [23] provides a simple descriptive profile and a single index score for general health status. We used this scale to measure participants' general health status. A converted index score ranges from −0.11 to 1.00: a score of 1 means "perfect health" and a score of 0 means "death."

To examine the changes in LBP status and overall health status over the 6-month period in each STarT-J risk group, we included two questions to assess the subjectively-perceived changes in health status: 1) How did your LBP status change compared with 6 months ago? and 2) How did your overall health status change compared with 6 months ago? Participants were asked to respond to each question on a 7-point scale: completely recovered, greatly improved, a little improved, not changed, a little worsened, greatly worsened, or became worst.

2.3. Statistical analysis

Demographic and clinical characteristics of participants at baseline were summarized for each STarT-J risk group using descriptive statistics. Demographic data included age, sex, body mass index, working status, smoking habits, and exercise habits.

For clinical outcomes, we calculated summary statistics for the pain NRS, RDQ, and EQ-5D scores at baseline and at 6-month follow-up for each STarT-J risk group. We performed an analysis of variance to test whether or not there were differences in scores between the three STarT-J risk groups (low-, medium-, and high-risk) at the 6-month follow-up.

Subjectively-perceived changes in health status were analyzed using a Cochran-Armitage trend test, by which we investigated whether there was a linear trend in the rate of improvement in LBP or overall health status across the STarT-J risk groups. In the analysis, the LBP or overall health status reported on the 7-point scale was interpreted as either improved or not improved: the responses "completely recovered" and "greatly improved" were considered improved, and the remaining 5 responses ("a little improved," "not changed," "a little worsened," "greatly worsened," and "became worst") as not improved.

All statistical analyses were performed using SAS version 9.3 (SAS Institute, Cary, NC, USA). The level of significance was set at 0.05.

3. Results

3.1. Participant characteristics

The present analysis included baseline and 6-month follow-up data of 1228 Japanese individuals. Table 1 presents a summary of the baseline demographic and clinical characteristics of the participants in each risk group. The mean (standard deviation [SD]) age of 1228 participants was 47.9 years (9.1 years) and 55.6% of participants were male. Based on STarT-J scores at baseline, participants were classified into three risk groups: 958 participants (78.0%) in the low-risk group, 176 participants (14.3%) in the medium-risk group, and 94 participants (7.7%) in the high-risk group. At baseline, the mean (SD) pain NRS score in the low-risk group was 3.8 (1.6), that in the medium-risk group was 5.2 (1.8), and that in the high-risk group was 6.2 (1.9). The mean (SD) RDQ score at baseline was 2.6 (3.2) in the low-risk group, 8.1 (4.9) in the medium-risk group, and 11.6 (6.7) in the high-risk group. Overall, four participants were considered to have LBP with specific pathologic change, 185 participants had LBP with radiating leg pain, and the remaining 1039 participants were considered to have LBP with non-specific causes.

3.2. Scores at 6-month follow-up

At the 6-month follow-up, the mean (SD) pain NRS score in the low-risk group was 3.9 (1.6), that in the medium-risk group was 5.0 (1.9), and in the high-risk group was 5.6 (1.9) (Fig. 2). Higher mean scores were observed in higher risk groups, and there were significant differences in scores among the three risk groups (the analysis of variance, $p < 0.0001$). The mean (SD) RDQ score at 6-month follow-up in the low-risk group was 2.1 (3.5), in the medium-risk group was 6.3 (5.6), and in the high-risk group was 9.6 (7.5) (Fig. 3). Again, the higher risk groups had higher scores, and the differences in scores among the three risk groups were significant (the analysis of variance, $p < 0.0001$). The mean (SD) EQ-5D index scores at 6-month follow-up were 0.86 (0.14), 0.73 (0.13), and 0.66 (0.20) for the low-, medium-, and high-risk groups respectively (Fig. 4). The higher risk groups had lower EQ-5D index scores, meaning that those who were classified in a higher risk group tended to report poorer health status. The between-group differences in EQ-5D index scores were also significant (the analysis of variance, $p < 0.0001$).

3.3. Changes in LBP and health status over 6 months

To investigate the actual chronicity of LBP at 6 months in each risk group, we evaluated participants' perception of their improvement in LBP and overall health status over 6 months. In total, 18.3% of participants in the low-risk group perceived improvement in LBP at 6-month follow-up, whereas 10.2% in the medium-risk group and 5.3% in the high-risk group perceived improvement. The statistical analysis showed a decreasing linear trend (the Cochran-Armitage trend test, $p < 0.0001$) (Fig. 5a). A similar trend was observed in the assessment of overall health

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Table 1
Baseline characteristics of participants in each STarT-J risk group (N = 1228).

Characteristics	Low-risk group (N = 958)	Medium-risk group (N = 176)	High-risk group (N = 94)
Age, years	48.0 (9.1)	47.4 (9.0)	48.1 (9.4)
Sex, male (n, %)	543 (56.7)	96 (54.5)	44 (46.8)
BMI ≥ 25 (kg/m^2) (n, %)	234 (24.4)	47 (26.7)	29 (30.9)
Job (n, %)			
With	714 (74.5)	132 (75.0)	53 (56.4)
Without	244 (25.5)	44 (25.0)	41 (43.6)
Current smoking habits (n, %)			
Yes	286 (29.9)	66 (37.5)	29 (30.9)
No	672 (70.1)	110 (62.5)	65 (69.1)
Exercise habits (n, %)			
Yes	236 (24.6)	37 (21.0)	16 (17.0)
No	722 (75.4)	139 (79.0)	78 (83.0)
Duration of low back pain (n, %)			
Less than 3 months	352 (36.7)	54 (30.7)	21 (22.3)
3 months or longer	606 (63.3)	122 (69.3)	73 (77.7)
Number of recurrence (n, %)			
First time	79 (8.2)	11 (6.3)	5 (5.3)
Second time	58 (6.1)	12 (6.8)	7 (7.4)
3 or 4 times	167 (17.4)	18 (10.2)	20 (21.3)
5 to 9 times	149 (15.6)	25 (14.2)	10 (10.6)
10 times or more	505 (52.7)	110 (62.5)	52 (55.3)
Pain NRS score	3.8 (1.6)	5.2 (1.8)	6.2 (1.9)
RDQ score	2.6 (3.2)	8.1 (4.9)	11.6 (6.7)
EQ-5D index score	0.82 (0.14)	0.66 (0.13)	0.61 (0.20)

Values are n (%) or mean (standard deviation). STarT-J: Japanese version of the STarT Back Tool. BMI: body mass index. NRS: numerical rating scale. RDQ: The Roland–Morris Disability Questionnaire. EQ-5D: The EuroQol 5 Dimension.

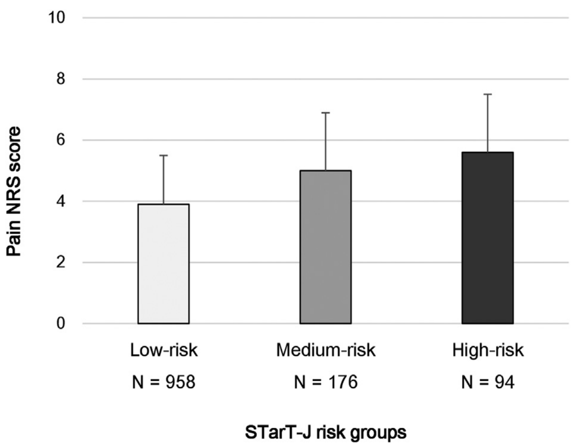

Fig. 2. Mean pain NRS scores at 6-month follow-up. Score differences among STarT-J risk groups were tested using analysis of variance (p < 0.0001). NRS: numerical rating scale. STarT-J: Japanese version of the STarT Back Tool.

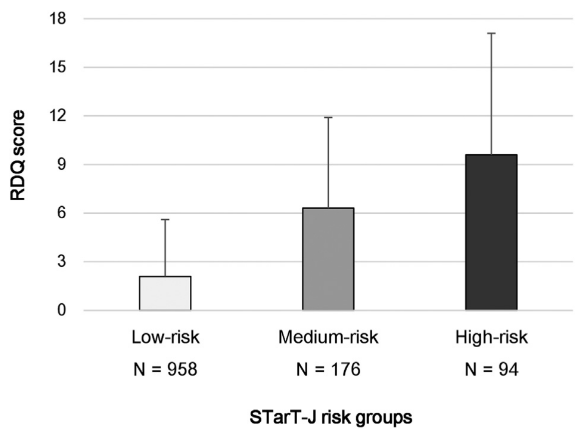

Fig. 3. Mean RDQ scores at 6-month follow-up. Score differences among STarT-J risk groups were tested using analysis of variance (p < 0.0001). RDQ: The Roland–Morris Disability Questionnaire. STarT-J: Japanese version of the STarT Back Tool.

status, with improvement perceived in overall health status at 6 months by 17.3%, 6.3%, and 4.3% of participants in the low-, medium-, and high-risk groups respectively. There was a decreasing linear trend in the improvement rate across the risk groups (the Cochran-Armitage trend test, $p < 0.0001$) (Fig. 5b).

4. Discussion

As psychological factors such as depression, fear-avoidance beliefs and behaviors, pain catastrophizing, and anxiety are known to be associated with chronicity of LBP [6], it is important to target and modify these prognostic factors at an early stage to improve the outcomes of LBP. A previous study showed that higher levels of fear-avoidance beliefs, kinesiophobia, and depressive symptoms were associated with non-recovery of LBP at 6 months [24]. The STarT is one tool that can assess these psychological factors in addition to LBP-related symptoms and physical impairment, and it stratifies patients into three risk groups based on the modifiable prognostic factors of their LBP. Considering that the STarT helps clinicians decide an appropriate therapeutic approach, it is important that the stratification is appropriate. Therefore in the present analysis, we assessed the 6-month clinical outcomes of patients stratified into each STarT-J risk group to evaluate whether the STarT-J appropriately predicted a poor prognosis of LBP (e.g. high-risk patients would be more likely to develop chronic LBP).

The results of the present analysis showed associations between the STarT-J high risk group and the poor 6-month clinical outcomes. The mean pain NRS scores were highest in the high-risk group and lowest in the low-risk group at the 6-month follow-up. This indicates that the STarT-J identified patients who would have greater pain at 6 months. The original STarT was able to predict pain at both 6 and 12 months in patients with non-specific LBP [25]. In addition, the mean RDQ scores at the 6-month follow-up were significantly

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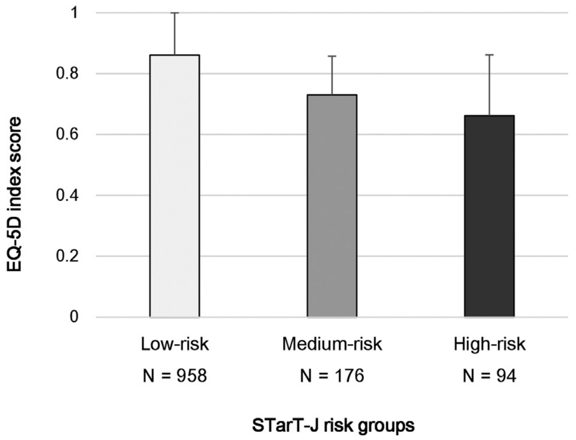

Fig. 4. Mean EQ-5D index scores at 6-month follow-up. Score differences among STarT-J risk groups were tested using analysis of variance ($p < 0.0001$). EQ-5D: The EuroQol 5 Dimension. STarT-J: Japanese version of the STarT Back Tool.

higher in the higher risk groups, indicating that similar to the original STarT, the STarT-J also detected patients with greater disability at 6 months [25]. Associations between the STarT risk groups and the long-term disability outcomes were reported in an analysis of the Danish version of the STarT [26]. In that analysis, the proportion of patients with a poor outcome (a RDQ score >30 on a 0–100 scale) at 3 months was highest in the high-risk group and lowest in the low-risk group. Although direct comparison is not appropriate given the different study designs, similar results were observed in the present analysis, with higher risk groups reporting poorer long-term disability outcomes.

Chronic LBP may be strongly related to patients' poor overall health status. In the present analysis, nearly 95% of participants in the high-risk group did not perceive sufficient improvement in LBP over 6 months, indicating a high possibility that these participants were suffering from chronic LBP. This risk group reported the least improvement in overall health status. Poor health status in this group was also shown by the lowest mean EQ-5D index score at the 6-month follow-up. Although the present analysis was unable to assess causal relationships between LBP and these variables, the results imply that chronic LBP may have a negative impact on patients' perception of their overall health status. Chronic LBP has been reported to have a negative impact on patients' psychological health, as well as their physical health [27]. Considering the potential negative impact of chronic LBP, our results highlight the importance of starting stratified care at an early stage, allowing modifiable risk factors (especially psychological factors) to be targeted in controlling the chronicity of LBP.

The major advantage of the STarT is in its simplicity. The tool is a 9-item self-report questionnaire for patients with non-specific LBP, which was developed to aid primary care decision making. As it is a quick tool, it would be helpful for clinicians, especially in primary care settings, to stratify patients according to their prognostic factors and decide which treatment strategy would be most appropriate (e.g., cognitive-behavioral therapy for high-risk patients). The STarT-J may therefore contribute to early stratified care in Japanese primary care settings.

The present analysis has some limitations. First, we observed a high attrition rate: in the follow-up survey, responses were received from 1228 of the 2000 participants who responded to the baseline survey. However, participants' characteristics in both analyses were similar and this was considered to represent a natural decline. A possible reason may be that participation in the survey was voluntary and no action was taken to achieve a high follow-up rate (e.g., e-mail reminders). Second, although participants were recruited according to the standard definition of LBP [21], the present analysis might have included patients not targeted by the STarT such as those with specific LBP causes. According to the diagnostic triage of LBP [28], responses indicated that four participants were probable “red flag,” who had LBP with specific pathologic change, but the remaining 1224 participants probably fit into the STarT target group. However, as these responses were based on participants' self-report, we cannot exclude the possibility of misclassification or misdiagnosis. Third, as this was an observational study and we did not interfere in participants' choice of treatment for LBP, outcomes at 6 months might have been influenced by a treatment that participants had received. Some participants reported to have received some treatment during the period, but others reported to have received no treatment. However, as information on the types of treatment was not collected in the

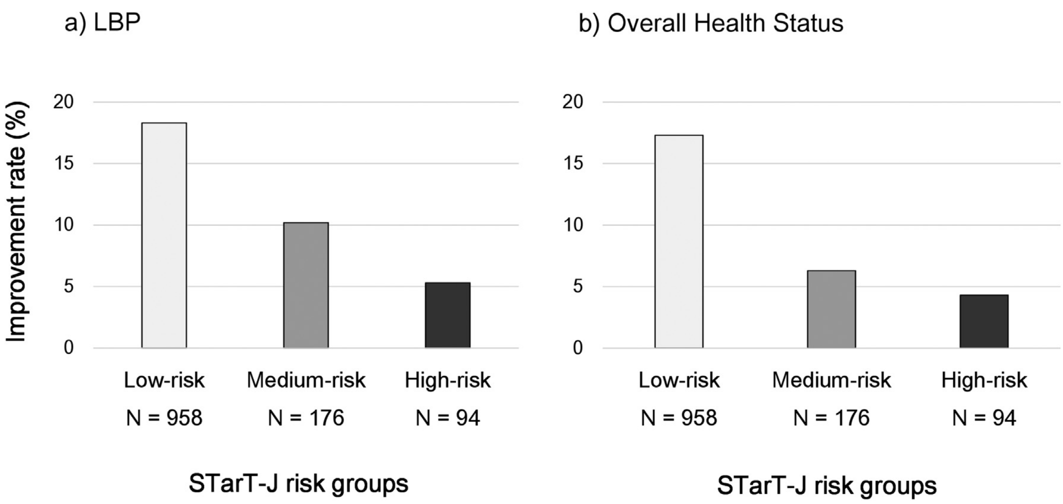

Fig. 5. Improvement rate of a) LBP and b) overall health status. Cochran-Armitage trend tests were performed to investigate the improvement rates ($p < 0.0001$ for both). LBP: low back pain. STarT-J: Japanese version of the STarT Back Tool.

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survey, actual treatment status of the individual participants is unknown. If participants had received effective treatments targeting modifiable indicators of LBP, it might have resulted in better outcomes compared to the natural course of LBP as predicted by the STarT-J at baseline. Therefore, the results of the present analysis need to be interpreted with care.

In conclusion, the STarT-J may help predict the 6-month prognosis of LBP, which allows classification of patients according to their risk for chronic LBP. Chronic LBP causes great disability and negatively affects patients' overall health status; therefore, it is important to start stratified care at an early stage in the management of non-specific LBP. The STarT-J is a simple, quick screening tool appropriate for use in primary care, which would enable and further promote early stratified care.

Conflict of interest statement

KM received grants from Ministry of Health, Labour and Welfare during the conduct of the study; grants from Sumitomo Dainippon Pharma Co., Ltd. and Okamura Corporation; grants and personal fees from AYUMI Pharmaceutical Corporation, Nippon Zoki Pharmaceutical Co., Ltd., Ono Pharmaceutical Co., Ltd., Eli Lilly Japan K.K., Astellas Pharma Inc., TOTO Ltd., and Eisai Co., Ltd.; personal fees and advisory fees from Shionogi & Co., Ltd.; and personal fees from Pfizer Japan Inc., Hisamitsu Pharmaceutical Co., Inc., Janssen Pharmaceutical K.K., Kaken Pharmaceutical Co., Ltd., and Teijin Pharma Limited, outside the submitted work.

HO received personal fees from Chugai Pharmaceutical Co., Ltd. and grants from Teijin Pharma Limited and Pfizer Japan Inc., outside the submitted work.

NK is a board member of Clinical Study Support, Inc.

YH and TS are employed by Clinical Study Support, Inc.

ST received personal fees from Amgen Inc., Asahi Kasei Pharma Corporation, Amgen Astellas BioPharma K.K., Ono Pharmaceutical Co., Ltd., KYOCERA Medical Corporation, Teijin Pharma Limited, and Eli Lilly Japan K.K.; endowments from Astellas Pharma Inc., AYUMI Pharmaceutical Corporation, Bristol-Myers Squibb, and Chugai Pharmaceutical Co., Ltd.; personal fees and endowments from Pfizer Japan Inc. and Daiichi Sankyo Company, Limited; and grants from The Japan Agency for Medical Research and Development (AMED), Grant-in-Aid for Scientific Research (A), and Grant-in-Aid for Exploratory Research, outside the submitted work.

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EPIDEMIOLOGICAL DIFFERENCES BETWEEN LOCALISED AND NON-LOCALISED LOW BACK PAIN

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ABSTRACT

Study design: Cross-sectional survey with longitudinal follow-up

Objectives: To test the hypothesis that pain which is localised to the low back differs epidemiologically from that which occurs simultaneously or close in time to pain at other anatomical sites

Summary of Background Data: Low back pain (LBP) often occurs in combination with other regional pain, with which it shares similar psychological and psychosocial risk factors. However, few previous epidemiological studies of LBP have distinguished pain that is confined to the low back from that which occurs as part of a wider distribution of pain.

Methods: We analysed data from CUPID, a cohort study that used baseline and follow-up questionnaires to collect information about musculoskeletal pain, associated disability and potential risk factors, in 47 occupational groups (office workers, nurses and others) from 18 countries.

Results: Among 12,197 subjects at baseline, 609 (4.9%) reported localised LBP in the past month, and 3,820 (31.3%) non-localised LBP. Non-localised LBP was more frequently associated with sciatica in the past month (48.1% vs. 30.0% of cases), occurred on more days in the past month and past year, was more often disabling for everyday activities (64.1% vs. 47.3% of cases), and had more frequently led to medical consultation and sickness absence from work. It was also more often persistent when participants were followed up after a mean of 14 months (65.6% vs. 54.1% of cases). In adjusted Poisson regression analyses, non-localised LBP was differentiallyassociated with risk factors, particularly female sex, older age and somatising tendency. There were also marked differences in the relative prevalence of localised and non-localised LBP by occupational group.

Conclusions: Future epidemiological studies should distinguish where possible between pain that is limited to the low back and LBP which occurs in association with pain at other anatomical locations.

Key Words: Low back pain; diagnostic classification; epidemiology; disability; medical consultation; sickness absence; sciatica; risk factors; somatising; occupation; prognosis

Level of Evidence: 2

INTRODUCTION

Low back pain (LBP) is a major cause of disability among people of working age [1], but investigation of its causes has been hindered by challenges in case definition. In most people with LBP, there is no clearly demonstrable underlying spinal pathology, and even where the pain occurs in association with structural abnormalities such as disc herniation or nerve root compression, only a minority of cases are attributable to theobserved pathology [2]. In the absence of more objective diagnostic criteria, most epidemiological studies have defined cases according to report of symptoms and/or accompanying disability,and this approach has given useful insights. For example, we know that LBP is associated with heavy lifting and other physical activities which subject the spine to mechanical stresses [3], although disappointingly, ergonomic interventions in the workplace to reduce such exposures have failed to prevent back problems [4]. Associations have also been found with psychological characteristics such as low mood [5-7], tendency to worry about common somatic symptoms (somatising tendency) [5,7], adverse health beliefs about musculoskeletal pain [6], and (to a lesser extent) psychosocial aspects of work [8].

The same psychological and psychosocial risk factors have been linked alsowith other regional musculoskeletal pain, for example in the upper limb [8,9] and knee [10]; and somatising tendency has shown particularly strong associations with multi-site pain [11]. Moreover, LBP frequently occurs in combination with pain at other anatomical sites, either simultaneously or close in time [12-15]. This raises the possibility that the observed associations of LBP with psychological and psychosocial risk factors might reflect effects on musculoskeletal pain more generally, and that pain which is limited only to the low back is epidemiologically distinct from that which occurs as part of a widerdistribution of pain. If this were the case, studies that failed to distinguish localised from non-localised LBP might miss associations with preventable causes, or incorrectly assess the impacts of treatment.

To test the hypothesis that localised and non-localised LBP are epidemiologically distinct, we analysed data from CUPID (Cultural and Psychosocial Influences on Disability), a large, multinational cohort study of musculoskeletal pain and associated disability in selected occupational groups [16], looking for differences in severity, associations with risk factors, and prognosis of LBP, according to whether or not pain was limited to the low back.

MATERIALS AND METHODS

The study sample for CUPID comprisedmen and women from 47 occupational groups (mainly nurses, office staff and workers carrying out repetitive manual tasks with their hands or arms) in 18 countries. Each of the 12,426 participants (overall response rate 70%) completed a baseline questionnaire, either by self-administration or at interview. The questionnaire was originally drafted in English and then translated into local languages as necessary, accuracy being checked by independent back-translation. Among other things, it asked about demographic characteristics, smoking habits, whether an average working day entailed lifting weights ≥25 kg, various psychosocial aspects of work, somatising tendency, mental health, beliefs about back pain, and experience of musculoskeletal pain during the past 12 months.

Somatising tendency was ascertained through questions taken from the Brief Symptom Inventory [17], and classified according to how many of five commonsomatic symptoms (faintness or dizziness, pains in the heart or chest, nausea or upset stomach, trouble getting breath and hot or cold spells) had caused at least moderate distress during the past week. Mental health was assessed through the relevant section of the Short Form 36 (SF-36) questionnaire [18], and scores were graded to three levels (good, intermediate or poor) representing approximate thirds of the distribution across the study sample. Participants were classed as having adverse beliefs about the work-relatedness of back pain if they completely agreed that such pain is commonly caused by work; about its relationship to physical activity if they completely agreed that for someone with back pain, physical activity should be avoided as it might cause harm, and that rest is needed to get better; and about its prognosis if they completely agreed that neglecting such problems can cause serious harm, and completely disagreed that such problems usually get better within three months.

The questions about musculoskeletal pain used diagrams to define 10 anatomical regions of interest (low back; neck; and right and left shoulder, elbow, wrist/hand and knee). Participants were asked whether during the past 12 months, they had experienced pain lasting for a day or longer at these sites, and those who reported LBP were also asked whether the pain had occurred in the past month, whether it had spread down the leg to below the knee (sciatica), how long in total it had been present during the past month and past 12 months, whether during the past month it had made it difficult or impossible to cut toe nails, get dressed or do normal jobs around the house(disabling pain), whether it had led to medical consultation during the past 12 months, the total duration of any resultant sickness absence from work during the past 12 months, and whether the most recent episode had started suddenly while at work, suddenly while not at work or gradually (an episode of pain was defined as occurring after a period of at least one month without the symptom).

After an interval of approximately 14 months, participants from 45 of the occupational groups were asked to complete a short follow-up questionnaire, which again asked about LBP in the past month.

Further details of the methods of data collection, specification of variables, and characteristics of the study sample have been reported elsewhere [16]. Approval for the study was provided by the relevant research ethics committees in each participating country [16].

Statistical analysis was carried out with Stata software (Stata Corp LP 2012, Stata Statistical Software: Release 12.1,College Station TX, USA). From the baseline questions about pain, we distinguished participants who reported: LBP in the past month but no pain at any other site during the past 12 months ("localised LBP"); LBP in the past month with pain at one or more other sites during the past 12 months ("non-localised LBP"); and no LBP at any time during the past 12 months. We used simple descriptive statistics to compare the features of localised and non-localised LBP, including the prevalence of continuing LBP (i.e. present in the past month) at follow-up. Associations with risk factors were explored by Poisson regression, and summarised by prevalence rate ratios (PRRs) with 95% confidence intervals (CIs) based on robust standard errors.To account for possible clustering by occupational group, we fitted random-intercept models. A scatter plot was used to explore the correlation of localised and non-localised LBP across the 47 occupational groups after adjustment for other risk factors. To derive adjusted prevalence rates, we took no LBP in the past 12 months as a comparator, and first estimated PRRs for the two pain outcomes in each occupational group relative to a reference (office workers in the UK),using Poisson regression models that included the other risk factors. We then calculated the "adjusted numbers" of participants in each occupational group with the two pain outcomes that would give crude PRRs equal to those estimated from the regression model. Finally, we used these adjusted numbers to calculate adjusted prevalence rates.

RESULTS

From the total of 12,426 participants who completed the baseline questionnaire, we excluded 149 because of missing information about LBP in the past month (122), 12 months (2) or both (25), and a further 80 who did not provide full responses regarding pain at other anatomical sites in the past 12 months. Among the remaining 12,197 subjects (35% men), 609 (5.0%) reported localised LBP in the past month, and 3,820 (31.3%) non-localised LBP.

Table 1 compares the characteristics of the pain in these two groups of people with low back symptoms. Non-localisedLBP was more frequently associated with sciatica (48.1% vs. 30.0% in past month), occurred on more days in the past month and past year, was more often disabling for everyday activities (64.1% vs. 47.3%), and had more frequently led to medical consultation and sickness absence from work during the past year. However, there was no difference between the categories of LBP in the prevalence of sudden as opposed to gradual onset.

Table 2 summarises the associations of localised and non-localised LBP with various risk factors.The comparator in this analysis was no LBP at any time in the past 12 months (n = 5,501). Non-localised LBP was significantly more common in women than men, and at older ages, whereas the prevalence of localised LBP was significantly higher in men, and varied little with age. Somatising tendency was much more strongly related to non-localised LBP (PRR 1.7, 95%CI 1.5-1.8 for report of distress from two or more somatic symptoms) than localised LBP (PRR 1.1, 95%CI 0.9-1.4). Associations with non-localised pain were stronger also for poor mental health and report of time pressure at work. Direct comparison of participants with localised and non-localised LBP in a single Poisson regression model (effectively taking those with non-localised LBP as cases and those with localised LBP as controls) indicated that the differences in associations with sex, age and somatising tendency were allhighly significantstatistically ($p < 0.001$).

Figure 1 shows the one-month prevalence of localised and non-localised LBP by occupational group, after adjustment for all of the risk factors in Table 2. Rates of localised LBP ranged from zero among postal workers in New Zealand and 1.0% in office workers in Nicaragua to 11.9% in Sri Lankan nurses, and 12.6% in Brazilian sugar cane cutters. For non-localised LBP, the absolute variation in prevalence was even greater – from 3.9% in Brazilian sugar cane cutters and 6.8% among office workers in Pakistan to 28.1% in Brazilian office workers and 28.8% in Brazilian nurses. However there was no clear relationship between the two categories of LBP. Thus, as illustrated in Figure 2, the proportion of all back pain cases that were localisedvaried substantially, but did not consistently rise or fall as the overall prevalence of LBP increased (Spearman correlation coefficient = –0.37).

Among the 11,764 participants from whom follow-up data were sought, 9,188 (78%) provided satisfactory information about LBP at a mean of14 months (range 3-35 months, 84% within 11-19 months) after baseline.Table 3 shows the prevalence of continuing LBP at follow-up according to the features of pain at baseline. Overall, persistence of pain was more frequent when initially it was non-localised (65.6%) than when it was localised (54.1%). Moreover, both categories of pain were more likely to be persistent if there was associated sciatica at baseline.

DISCUSSION

In this large international study, we found that most LBP (86%) was non-localised. In comparison with localised LBP, non-localised LBP tended to be more troublesome, disabling and persistent, and showed distinctive associations with risk factors. In addition, the two categories of LBP differed markedly in their relative prevalence across the 47 occupational groups that were studied.

Apart from occupational group, all of the information that was analysed came from questionnaires. Pain, somatising tendency, mental health and health beliefs are all best assessed through self-report. However, it is possible that reliance on participants' recall led to inaccuracies in other variables such as smoking habitsand exposure to heavy lifting at work. If so, the impact on risk estimates will have depended on whether errors differed systematically according to report of pain. If they were non-differential with respect to pain, then any resultant bias will have been towards the null. On the other hand, if they varied by pain status (e.g. if participants with LBP tended to report heavy lifting more completely than those who were pain-free), then risk estimates could have been spuriously exaggerated. However, even if such biases occurred, it seems unlikely that they would have differed importantly according to whether or not LBP was localised.

A particular methodological challenge in the CUPID study was the possibility that despite our efforts to minimise errors in translation of the questionnaires, terms for pain might be understood differently in different cultures. However, misunderstandings are less likely to have occurred in determining the anatomical location of symptoms, which was assisted by the use of diagrams. Thus, while some of the differences between occupational groups in the overall prevalence of LBP may have been a linguistic artefact, variations in the proportion of LBP that was localised are likely to be more reliable.

It seemsunlikely that the differences which we found between localised and non-localised LBP could be explained by selective participation in the study. Eligibility for inclusion depended only on participants' employment in designated jobs and being in the specified age range, and response rates were relatively high both at baseline and at follow-up. Moreover, we can think of no reason why responders should differ from non-responders differentially in relation to associations with non-localised as compared with localised LBP.

In comparison with localised LBP, non-localised LBP was more persistent and more often a cause of disability, sickness absence from work and medical consultation.This accords with the observation in a Dutch study that among industrial workers with LBP, those whose pain was disabling or had lasted for longer than three months were more likely to have musculoskeletal co-morbidity [14], although in that investigation rates of sickness absenceand medical care-seeking were only marginally higher in subjects whose LBP was accompanied by pain in the upper extremity. Also, in a community-based Norwegian investigation, functional ability was better among participants with localised LBP than in those who reported LBP as part of widespread pain [12]. These differences may occur because people who report pain at multiple sites have a generally lower threshold for awareness and intolerance of symptoms.

Before performing our analysis, we speculated that sudden onset and associated sciatica might be indications that LBP arises from acute injury or other localised spinal pathology, and therefore would be more common among people with localised LBP. However, we found no evidence for such a relationship. On the contrary, sciatica was more prevalent among participants with non-localised LBP than in those whose LBP was localised.

Previous analysis of the CUPID dataset has indicated that multi-site musculoskeletal pain is more common in women than men, and at older ages [15]. It is therefore unsurprising that non-localised LBP showed similar associations. In marked contrast, however, localised LBP was more frequent among men than women, and tended to have higher prevalence at younger ages. This is consistent with findings from a community-based survey in Norway [12].

After adjustment for sex and age, both localised and non-localised LBP were associated with smoking, heavy lifting, somatising tendency, poor mental health, adverse beliefs about occupational causation and the prognosis of LBP, and less clearly with some psychosocial aspects of work (Table 2). Because the analysis was cross-sectional, these associations cannot necessarily be interpreted as causal, although they are consistent with findings from other studies [3,5-8,19,20]. Of greater interest are the differences in the strength of the relationships according to whether LBP was localised or associated with pain at other anatomical sites. As well as somatising tendency, poor mental health and several psychosocial aspects of work showed significantly stronger associations with non-localised LBP. This could occur if the psychological risk factors were associated with proneness to pain more generally, and not specifically in the low back.

We are aware of only one other study that has compared the epidemiology of localised and non-localised LBP [12], and that did not investigate multiple risk factors as we have done. However, a prospective cohort study in Germany of patients whoconsulted general practitionerswith chronic LBP, but in whom pain was not at the time widespread, found that transition to chronic widespread pain at follow-up was associated with female sex and a high rate of psychosomatic symptoms

[21,22]. Non-localised LBP, as we defined it, would not necessarily be classed as chronic widespread pain – the pain may have occurred at only one other anatomical site in addition to the low back, and may have been only short-lived. Moreover, we do not know whether the onset of pain in the low backpreceded or followed that at other anatomical sites. Nevertheless, our observation that non-localised LBP was differentially associated with female sex and somatising tendency is consistent with the results of the German study.

When the risk factors in Table 2 were taken into account, there were also marked differences in the relative prevalence of localised and non-localised LBP by occupational group. Thus the proportion of LBP that was localised varied from zero in New Zealand postal workers to 76.4% among sugar cane cutters in Brazil, with a tendency to be lower when the overall prevalence of LBP was higher (Figure 2). This again is an indication that localised LBP is epidemiologicallydistinct.

Our study sample was limited to men and women in employment, and we cannot be certain that the differences which were found between localised and non-localised LBP in severity, associations with risk factors, and prognosis, would be the same in all populations. However, their observation in a large sample of workers from 18 countries across five continents is sufficient to demonstrate that potentially important epidemiological differences do occur.Thissuggests that where possible, epidemiological studies on the causes andprognosis of LBPshould distinguish pain that is limited to the low back from that which occurs in association with pain at other anatomical locations.

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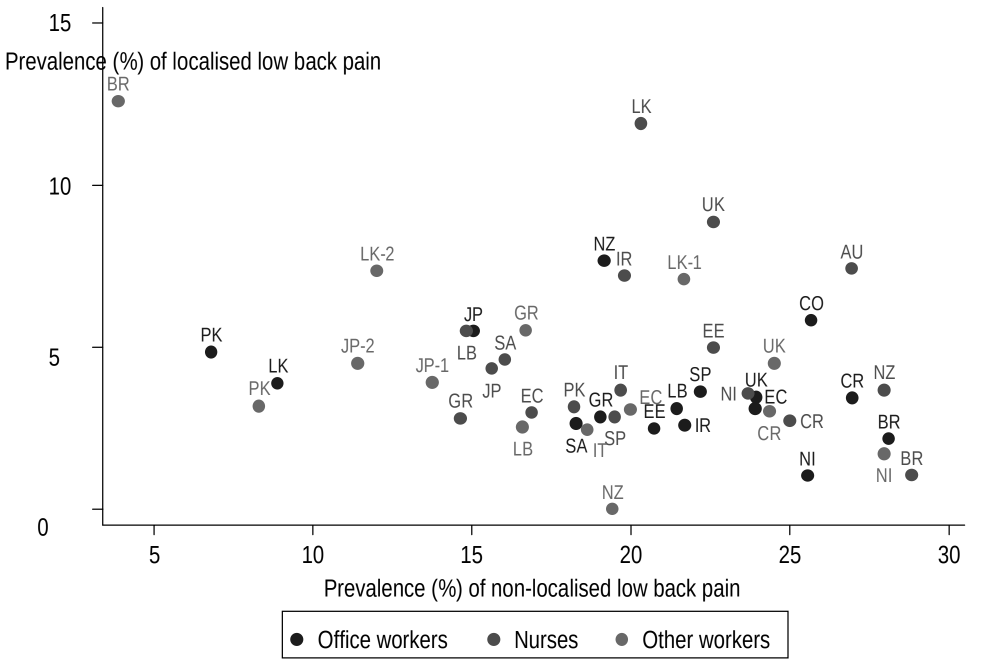
Figure 1 One-month prevalence of localised and non-localised low back pain by occupational group

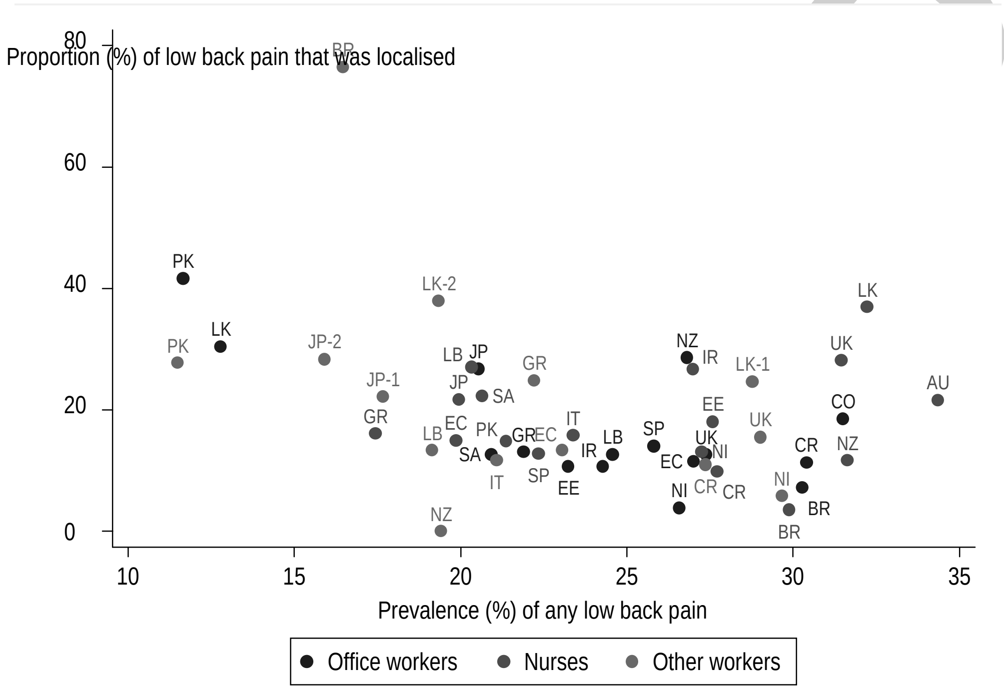
Prevalence rates are adjusted for all of the risk factors in Table 2



Key to countries: AU Australia; BR Brazil; CO Colombia; CR Costa Rica; EC Ecuador; EE Estonia; GR Greece; IR Iran; IT Italy; JP Japan; LB Lebanon; LK Sri Lanka; NI Nicaragua; NZ New Zealand; PK Pakistan; SA South Africa; SP Spain; UK United Kingdom

Figure 2 Proportion of low back pain that was localised according to overall prevalence of low back pain in each occupational group

Prevalence rates are adjusted for all of the risk factors in Table 2



Key to countries: AU Australia; BR Brazil; CO Colombia; CR Costa Rica; EC Ecuador; EE Estonia; GR Greece; IR Iran; IT Italy; JP Japan; LB Lebanon; LK Sri Lanka; NI Nicaragua; NZ New Zealand; PK Pakistan; SA South Africa; SP Spain; UK United Kingdom

Table 1 Characteristics of localised and non-localised low back pain

Characteristic	Localised low back pain (n = 609)			Non-localised low back pain (n = 3,820)		
	N	%	(95%CI)	N	%	(95%CI)
Sciatica in past month	183	30.0	(26.4,33.9)	1,836	48.1	(46.5,49.7)
Sciatica in past 12 months	233	38.3	(34.4,42.3)	2,238	58.6	(57.0,60.2)
Total duration in past month						
1-6 days	369	60.6	(56.6,64.5)	2,067	54.1	(52.5,55.7)
1-2 weeks	123	20.2	(17.1,23.6)	783	20.5	(19.2,21.8)
>2 weeks	112	18.4	(15.4,21.7)	947	24.8	(23.4,26.2)
Not known	5	0.8		23	0.6	
Total duration in past 12 months						
1-6 days	180	29.6	(26.0,33.4)	740	19.4	(18.1,20.7)
1-4 weeks	263	43.2	(39.2,47.2)	1,661	43.5	(41.9,45.1)
1-12 months	162	26.6	(23.1,30.3)	1,403	36.7	(35.2,38.3)
Not known	4	0.7		16	0.4	
Disabling in past month	288	47.3	(43.3,51.3)	2,447	64.1	(62.5,65.6)

Led to medical consultation in past 12 months	255	41.9	(37.9,45.9)	1,974	51.7	(50.1,53.3)
Attributed sickness absence in past 12 months (days)						
0	475	78.0	(74.4,81.2)	2,707	70.9	(69.4,72.3)
1-5	83	13.6	(11.0,16.6)	674	17.6	(16.4,18.9)
6-30	29	4.8	(3.2,6.8)	238	6.2	(5.5,7.0)
>30	10	1.6	(0.8,3.0)	85	2.2	(1.8,2.7)
Not known	12	2.0		116	3.0	
Onset of most recent episode						
Sudden while at work	167	27.4	(23.9,31.2)	1,176	30.8	(29.3,32.3)
Sudden not while at work	110	18.1	(15.1,21.4)	530	13.9	(12.8,15.0)
Gradual	318	52.2	(48.2,56.2)	2,015	52.7	(51.2,54.3)
Not known	14	2.3		99	2.6	

Table 2 **Associations of localised and non-localised low back pain with personal and occupational risk factors**

Risk factor	No low back pain in past 12 months	Localised low back pain			Non-localised low back pain		
	N	N	PRR[a]	(95%CI)	N	PRR[a]	(95%CI)
Sex							
Male	2,265	292	1		943	1	
Female	3,236	317	0.8	(0.6,0.9)	2,877	***1.2	(1.1,1.3)
Age (years)							
20-29	1,502	175	1		783	1	
30-39	1,737	208	1.0	(0.8,1.2)	1,189	**1.1	(1.1,1.2)
40-49	1,446	147	0.9	(0.7,1.1)	1,203	***1.2	(1.1,1.4)
50-59	816	79	0.9	(0.7,1.1)	645	***1.2	(1.1,1.4)

Smoking							
Never smoked	3,631	339	1		2,349	1	
Ex-smoker	727	91	1.3	(1.0,1.7)	579	1.1	(1.1,1.2)
Current smoker	1,124	176	1.3	(1.0,1.7)	885	1.1	(1.1,1.3)
Not known	19	3			7		
Activity in average working day							
Lifting weights ≥25 kg	1,684	266	1.4	(1.2,1.7)	1,599	1.2	(1.1,1.3)
Psychosocial aspects of work							
Work for >50 hours per week	1,394	176	1.0	(0.8,1.3)	601	†1.0	(0.9,1.1)
Time pressure at work	3,948	456	1.0	(0.8,1.2)	3,046	*1.2	(1.1,1.3)
Incentives at work	1,605	168	0.9	(0.7,1.1)	1,054	1.0	(0.9,1.1)

Lack of support at work	1,104	126	1.0	(0.8,1.3)	1,190	**1.1	(1.0,1.2)
Job dissatisfaction	1,087	128	0.9	(0.8,1.1)	817	1.0	(0.9,1.2)
Lack of job control	1,136	134	1.1	(0.9,1.3)	864	1.0	(1.0,1.1)
Job insecurity	1,652	220	1.1	(1.0,1.3)	1,277	1.1	(1.0,1.2)
Number of distressing somatic symptoms in past week							
0	3,871	406	1		1,631	1	
1	983	127	1.2	(1.0,1.5)	943	***1.4	(1.3,1.5)
2+	596	70	1.1	(0.9,1.4)	1,200	***1.7	(1.5,1.8)
Missing	51	6			46		
Mental health							
Good	2,417	225	1		1,137	1	
Intermediate	1,628	181	1.1	(0.9,1.3)	1,157	1.2	(1.1,1.3)

Poor	1,418	198	1.2	(1.0,1.5)	1,504	**1.4	(1.3,1.5)
Missing	38	5			22		
Adverse beliefs about back pain							
Work-relatedness	1,472	215	1.3	(1.1,1.5)	1,617	*1.3	(1.2,1.3)
Physical activity	999	119	0.9	(0.7,1.1)	669	0.9	(0.9,1.0)
Prognosis	598	86	1.2	(1.0,1.4)	709	**1.2	(1.1,1.3)

[a]Prevalence rate ratios relative to no low back pain in past 12 months derived from a single Poisson regression model for each pain outcome, with random intercept modelling to allow for clustering by occupational group

*Risk significantly higher for non-localised when compared directly with localised low back pain (p<0.05)

**Risk significantly higher for non-localised when compared directly with localised low back pain (p<0.01)

***Risk significantly higher for non-localised when compared directly with localised low back pain (p<0.001)

†Risk significantly lower for non-localised when compared directly with localised low back pain (p<0.01)

Table 3 **One-month prevalence of low back pain at follow-up according to localisation of low back pain at baseline**

Analysis was restricted to the 9,188 cases with satisfactory information about low back pain at follow-up

Category of low back pain at baseline	Number of cases at baseline	Low back pain in past month at follow-up	
		Number of cases	Prevalence % (95%CI)
Localised with no sciatica in past 12 months	282	144	51.1 (45.1,57.0)
Localised with sciatica in past 12 months	158	94	59.5 (51.4,67.1)
All localised low back pain	440	238	54.1 (49.3,58.8)
Non-localised with no sciatica in past 12 months	1,199	718	59.9 (57.0,62.6)
Non-localised with sciatica in past 12 months	1,695	1,181	69.7 (67.4,71.8)
All non-localised low back pain	2,894	1,899	65.6 (63.8,67.4)

ORIGINAL ARTICLE

Development of the Japanese Version of the Leeds Assessment of the Neuropathic Symptoms and Signs Pain Scale: Diagnostic Utility in a Clinical Setting

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■ **Abstract**

Objective: We aimed to assess the diagnostic utility of the linguistically validated Japanese version of the Leeds Assessment of Neuropathic Symptoms and Signs Pain Scale (LANSS-J) as a screening tool for neuropathic pain in the clinical setting.
Methods: Patients with neuropathic pain or nociceptive pain who were 20 to 85 years of age were included. Sensitivity and specificity using the original cutoff value of 12 were assessed to evaluate the diagnostic utility of the LANSS-J. Sensitivity and specificity with possible cutoff values were calculated, along with area under the receiver operating characteristic curve. We then evaluated agreement regarding assessment of the LANSS-J by two investigators. We used the intraclass correlation coefficient (ICC) for the total score and Cohen's kappa coefficient for each item.
Results: Data for patients with neuropathic pain (n = 30) and those with nociceptive pain (n = 29) were analyzed. With a cutoff of 12, the sensitivity was 63.3% (19/30) and the specificity 93.1% (27/29). Sensitivity improved substantially with a cutoff of $\leq$ 11 ($\geq$ 83.3%, 25/30). High specificity (93.1%, 27/29) was sustained with a cutoff of 9 to 12. The ICC for the total score was 0.85, indicating sufficient agreement. Kappa coefficients ranged from 0.68 to 0.84.
Conclusions: The LANSS-J is a valid screening tool for detecting neuropathic pain. Our results suggest that

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employing the original cutoff value provides high specificity, although a lower cutoff value of 10 or 11 (with its high specificity maintained) may be more beneficial when pain attributed to neuropathic mechanisms is suspected in Japanese patients. ■

Key Words: neuropathic pain, Leeds Assessment of Neuropathic Symptoms and Signs Pain Scale, Japanese version, screening tools, diagnostic utility

INTRODUCTION

Neuropathic pain is defined as "pain caused by a lesion or disease of the somatosensory nervous system."[1] Neuropathic pain negatively affects physical functioning, emotional functioning (eg, depression, anxiety), sleep, and role and social functioning.[2] Unsurprisingly, health-related quality of life is lower in patients with chronic neuropathic pain than in those with chronic non-neuropathic pain.[3,4]

Although an appropriate diagnosis is essential for successful management of neuropathic pain, the diagnosis is challenging because neuropathic pain often coexists with other types of pain and symptoms.[5] Neuropathic pain mostly presents at and is managed in a primary care setting or in hospital clinics by nonspecialists.[6] Hence, a reliable, quick screening tool could help these nonspecialists identify patients with neuropathic pain.

The Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) Pain Scale was developed as a screening questionnaire to differentiate patients with neuropathic pain from those with nociceptive pain.[7] It consists of seven items: five items for assessing pain and two items for sensory examination. For pain assessment, clinicians interview patients with questions on dysesthesia, autonomic dysfunction, evoked pain, paroxysmal pain, and thermal pain. For the sensory examination, the clinician tests for the presence of allodynia and for an altered pinprick threshold (PPT). The total score (sum of the 7-item scores) ranges from 0 to 24 points. A total score of ≥ 12 indicates that neuropathic mechanisms are likely contributing to the patient's pain.[7]

The original English language version of the LANSS Pain Scale is known to have high diagnostic accuracy.[7,8] It has been translated and widely used in several languages, including Turkish, Spanish, Swedish, Chinese, and Brazilian Portuguese.[9–14] In a previous study, we translated the LANSS Pain Scale into Japanese (LANSS-J) and validated it linguistically, after obtaining development permission from the original developer, Dr. Michael I. Bennett.[15] Its diagnostic utility as a screening tool, however, has not yet been assessed. Therefore, in this study we evaluated the diagnostic utility of the LANSS-J to determine whether it can be used as a screening tool in the clinical setting in Japan.

METHODS

The study was approved by the Ethics Committee (an investigational review board) of the University of Tokyo in January 2015. Written informed consent was obtained from each eligible participant.

Participants

Patients with neuropathic pain or nociceptive pain who were 20 to 85 years of age were included in this study. Patients with neuropathic pain were included only if their chief complaint was diagnosed as pain of neuropathic origin, which included diabetic peripheral neuropathy, postherpetic neuralgia, trigeminal neuralgia, and postchemotherapy neuropathy. Patients with nociceptive pain were included only if their chief complaint was diagnosed as nociceptive pain, such as osteoarthritis of the knee or hip.

Patients with neuropathic pain were excluded if they had clear comorbidity-related nociceptive symptoms, including bruises or joint pain derived from osteoarthritis. Patients with nociceptive pain were excluded if they had clear comorbidity-related neuropathic symptoms such as that derived from diabetes under treatment, intervertebral disk herniation (positive straight leg raising test, $< 70°$), or lumbar spinal stenosis (positive Kemp test). Patients who had mixed pain, a psychiatric disorder, dementia, fever, or menstrual pain, those who were incapable of understanding and completing the questionnaires by themselves, and those who were deemed inappropriate for participation by the investigators were also excluded.

Data Collection

After ethical approval was obtained, participants were recruited from March through July 2015 at two departments of the University of Tokyo Hospital. Patients with neuropathic pain were recruited at the Department of Anesthesiology and Pain Relief Center and patients with nociceptive pain at the Department of Orthopaedic Surgery and Spinal Surgery.

The attending doctor (primary investigator) interviewed each patient to assess pain using the LANSS-J. The patient then completed two self-administered questionnaires: the Japanese version of the painDETECT questionnaire (PDQ-J) and the EuroQol 5 Dimension (EQ-5D). Another doctor (secondary investigator) then administered the same LANSS-J to the patient on the same day.

The primary investigator collected the demographic and clinical characteristics of each patient. For the original LANSS Pain Scale, the PPT was assessed using a 23-gauge needle. In this study, however, a partially extended paper clip (instead of the needle) was used to avoid injuring the skin.

The PDQ-J is a reliable, valid screening tool for identifying neuropathic pain. It was originally developed in Germany to detect neuropathic pain components in patients with chronic low back pain.[16] A total PDQ-J score ranges from 0 to 38. Scores of $\leq$ 12 indicate that it is unlikely that neuropathic pain is present. Scores of $\geq$ 19 indicate that it is highly likely that neuropathic pain is present.

The EQ-5D is a 5-item, self-administered questionnaire that provides a single index value for the general health status of the respondent.[17] The Japanese version of the EQ-5D has been widely used in research. The index score produced by conversion of the assessed health status ranges from −0.11 to 1.00. A score of 1 indicates "perfect health," and a score of 0 indicates "death."

Statistical Analysis

We performed descriptive analyses of demographic and clinical characteristics of patients. Summary statistics on age, sex, diagnosis, time since diagnosis, body mass index (BMI), PDQ-J score, and EQ-5D score were calculated for patients with neuropathic pain and those with nociceptive pain.

The sensitivity and specificity of the LANSS-J were assessed using data collected by the primary investigators to evaluate its diagnostic utility. The scoring method of the original LANSS Pain Scale was utilized. Using the same cutoff value as for the original LANSS Pain Scale, the sensitivity and specificity of the LANSS-J were computed. Sensitivity was the percentage of patients with a LANSS-J score of $\geq$ 12 among those with a diagnosis of neuropathic pain. Specificity was the percentage of patients with a LANSS-J score of < 12 among those with a diagnosis of nociceptive pain, along with the area under the receiver operating characteristic curve (AUC). To assess changes in the screening results of the LANSS-J that depended on a cutoff value, we calculated the sensitivity and specificity with possible cutoff values and AUCs.

Subsequently, the intraclass correlation coefficient (ICC) value for the LANSS-J total score was calculated to evaluate agreement of the assessments by the primary and secondary investigators using data collected on the same day. In addition, Cohen's kappa was calculated for each item to assess agreement of the assessments by investigators. An ICC of $\geq$ 0.7 was considered the minimum required.[18] The kappa coefficients were interpreted according to the following criteria: poor, < 0.20; fair, 0.21 to 0.40; moderate, 0.41 to 0.60; good, 0.61 to 0.80; and very good, 0.81 to 1.00.[19,20]

All of the statistical tests were 2-sided, with a significance level of 0.05. All analyses were performed using SAS software version 9.3 (SAS Institute, Inc. Cary, NC, USA).

RESULTS

A total of 60 patients were included in the study. Among them, one patient had missing responses to the LANSS-J. Therefore, our final study group was composed of 59 patients (Figure 1). In all, 30 patients (50.8%) were diagnosed with neuropathic pain and 29 patients (49.2%) with nociceptive pain while waiting for knee or hip replacement surgery. Demographic and clinical characteristics of the patients are summarized by pain type in Table 1. The neuropathic pain patients were younger, included more men, had a longer interval since diagnosis, and had a higher average PDQ-J score than the nociceptive pain group. BMI did not differ greatly between the two groups. Detailed etiologies of the diagnoses are shown in Table 2.

Employing the cutoff value of 12, as suggested by the original developer, the sensitivity of the LANSS-J for diagnosing neuropathic pain was 63.3% (19/30), and the specificity of the scale for diagnosing nociceptive pain was 93.1% (27/29) (Table 3). The AUC for the cutoff value was 0.782.

Table 3 shows the sensitivity, specificity, and AUC for each possible LANSS-J cutoff value. The sensitivity of the scale substantially improved with a cutoff value of 11 (83.3%, 25/30), whereas the specificity was unchanged using cutoff values of 12 descending to 9 (93.1%, 27/29).

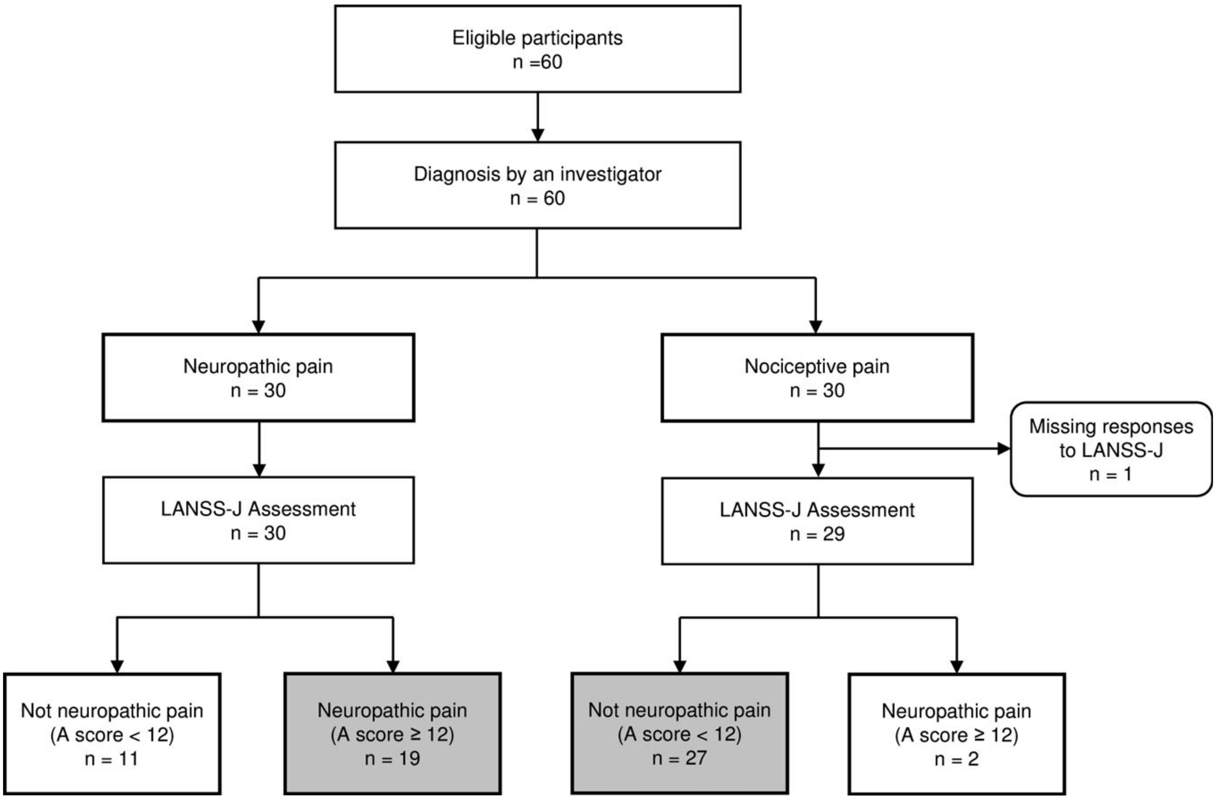

Figure 1. Flow diagram of participants in the study. The diagnostic flow diagram shows the case when using a cutoff value of 12 for the Japanese version of the Leeds Assessment of Neuropathic Symptoms and Signs Pain Scale (LANSS-J). A LANSS-J score of ≥ 12 indicates the probable pain originating from neuropathic mechanisms. A score of < 12 indicates the probable pain not originating from neuropathic mechanisms.

Table 1. Demographic and Clinical Characteristics of Participants, by Pain Type

Characteristics	Neuropathic Pain Group (*n* = 30)	Nociceptive Pain Group (*n* = 29)
Mean years of age (SD)	56.4 (12.9)	70.5 (8.6)
Female, *n* (%)	10 (33.3)	26 (89.7)
Mean months since diagnosis (SD)	94.4 (89.9)	67.6 (50.8)
Mean BMI (kg/m^2) (SD)	23.2 (3.7)	25.0 (4.1)
Mean PDQ-J score (SD)	18.1 (5.4)	5.0 (5.6)
Mean EQ-5D score (SD)	0.4 (0.3)	0.6 (0.1)

BMI, body mass index, PDQ-J, Japanese version of the painDETECT Questionnaire; EQ-5D, EuroQol 5 Dimension.

Agreement of the Assessments by Investigators

Agreement in the assessment of the LANSS-J by the primary and secondary investigators was reflected in an ICC of 0.85 using data from 51 patients (28 neuropathic pain patients, 23 nociceptive pain patients) in whom the assessments were conducted on the same day. The kappa coefficient for agreement between investigators for individual items was 0.71 for dysesthesia, 0.84 for autonomic dysfunction, 0.69 for evoked pain, 0.76 for paroxysmal pain, 0.80 for thermal pain, 0.68 for allodynia, and 0.80 for altered PPT.

DISCUSSION

We assessed the diagnostic utility of the LANSS-J using data collected from Japanese patients with neuropathic or nociceptive pain. The results suggest that the LANSS-J had debatable sensitivity when it employed the cutoff value used for the original LANSS Pain Scale but good specificity and agreement of the assessments.

The sensitivity using the original cutoff value was lower (63.3%) than that for the original LANSS (85.0%) or for LANSS versions in other languages (80.0% to 89.9%), whereas the specificity was higher (93.1%) than that for the original LANSS (80.0%) and Spanish LANSS (89.4%) but lower than for the Turkish (94.2%) and Chinese (97.1%) versions.[7,9,10,12] The

Table 2. Etiology of Patients' Diagnoses

Etiology	Neuropathic Pain Group (n = 30)	Nociceptive Pain Group (n = 29)
Complex regional pain syndrome II	1	
Failed back surgery syndrome	5	
Diabetic polyneuropathy	1	
Chemotherapy-induced neuropathy	1	
Traumatic radial nerve injuries	1	
Syringomyelia	1	
Cervical spondylotic myelopathy	2	
Cervical spondylotic radiculopathy	1	
Cervical radiculopathy	1	
Vascular polyneuropathy	1	
Phantom limb pain	1	
Thalamic pain	3	
Spinal cord injuries induced by metastatic tumor	1	
Diabetic neuropathy	1	
Postoperative neuropathy (mammary gland)	1	
Brachial plexus injury	7	
Brachial plexus palsy	1	
Knee osteoarthritis		15
Hip osteoarthritis		14

Table 3. Sensitivity and Specificity of Possible Cutoff Values with the AUC

Cutoff Value	Sensitivity % (n/N Patients)	Specificity % (n/N Patients)	AUC
≥ 0	100 (30/30)	0 (0/29)	0.500
≥ 3	100 (30/30)	65.5 (19/29)	0.828
≥ 6	100 (30/30)	72.4 (21/29)	0.862
≥ 9	90.0 (27/30)	93.1 (27/29)	0.916
≥ 10	86.7 (26/30)	93.1 (27/29)	0.899
≥ 11	83.3 (25/30)	93.1 (27/29)	0.882
≥ 12	63.3 (19/30)	93.1 (27/29)	0.782
≥ 13	63.3 (19/30)	93.1 (27/29)	0.782
≥ 14	63.3 (19/30)	93.1 (27/29)	0.782
≥ 15	60.0 (18/30)	93.1 (27/29)	0.766
≥ 18	46.7 (14/30)	96.6 (28/29)	0.716
≥ 21	16.7 (5/30)	96.6 (28/29)	0.566

AUC, area under the receiver operating characteristic curve.

sensitivity was lower in the present study probably because patients with severe traumatic nerve injury were included in the neuropathic pain group. Because of the severe nerve damage in these patients, evoked pain and allodynia could barely be perceived. In fact, among the 30 patients, 15 and 17 patients provided a negative response to the descriptors of evoked pain and allodynia, respectively. Traumatic nerve injury does not entail changes in the color of the skin attributable to impaired blood flow or hyperpigmentation, unlike diabetic

Table 4. Agreement of LANSS-J Assessments Between the Two Investigators, by Cutoff Values

Cutoff Value	Kappa	No. of Patients Correctly Identified by the LANSS-J in Two Assessments: Neuropathic Pain (n = 28)	Nociceptive Pain (n = 23)
≥ 12	0.65	17	21
≥ 11	0.80	23	21
≥ 10	0.84	24	21

Cohen's kappa coefficients were computed to evaluate the agreement in screening results (either neuropathic or non-neuropathic pain) between the two assessments based on the LANSS-J total scores for a cutoff value of 12, 11, and 10.
LANSS-J, Japanese version of the Leeds Assessment of Neuropathic Symptoms and Signs Pain Scale.

neuropathy and postherpetic neuralgia. Among the 30 patients in the neuropathic pain group, 17 reported a negative response to the descriptors of autonomic dysfunctions. It is legitimate that a score of evoked pain in the PDQ-J was also low in the neuropathic pain group —the third lowest score in seven pain categories—but as low as the second lowest pain caused by slight pressure. Hence, lower scores for evoked pain, allodynia, and autonomic dysfunction in patients with neuropathic pain presumably resulted in the lower sensitivity.

Another possible explanation for the lower sensitivity is that the patients did not openly express their feelings about the pain they felt. In traditional Japanese culture, stoicism and the desire to conceal pain and emotions are expected—unlike in European and American cultures, where expressing personal feelings is encouraged.[21]

The sensitivity was lower when using the original cutoff value of 12, whereas specificity was favorable. Exploration of a possible cutoff value shows that using a value of 10 or 11 alone improved sensitivity while leaving the specificity unchanged (sensitivity 86.7% and 83.3%, respectively; specificity 93.1% for both values; AUC 0.899 and 0.882, respectively). Given that the lower sensitivity in the LANSS-J, compared with that of the LANSS in other languages, results not only from the number of patients with traumatic nerve injuries included in the present study but also from cultural influences on their verbal expression, physicians conducting screening should suspect neuropathic components in the pain in patients whose LANSS-J score is 10 or 11.

For agreement of the LANSS-J assessments by two investigators, the ICC for the total LANSS-J score exceeded the sufficient level of 0.7.[22] The Spanish and Brazilian Portuguese versions indicated relatively higher ICCs (0.92 and 0.97, respectively) than were seen in the present results.[10,13] Regarding individual items, the kappa coefficients, ranging from 0.68 for allodynia to 0.84 for autonomic dysfunction, indicated good to very good levels of agreement,[19] which is equivalent to the results of the original LANSS Pain Scale (0.6 for dysesthesia, 0.88 for autonomic dysfunction).[7] When looking at the ICCs in each pain group, however, compared with the ICC in the neuropathic pain group, the ICC in the nociceptive pain group was lower (0.81 vs. 0.22). Therefore, we further evaluated whether score changes between the two assessments resulted in a change in the screening results by the LANSS-J or if the LANSS-J screening results remained the same for the two assessments. The results were presented in Table 4. When employing the original cutoff value of 12, the kappa coefficient was 0.65, which is regarded as a good level, with 17 of 28 patients in the neuropathic pain group remaining positive, whereas 21 of 23 patients in the nociceptive pain group remained negative.

The results of further examinations depended on the cutoff point employed. The results suggest that a lower cutoff value may be more helpful for detecting neuropathic pain in a Japanese population. Similarly, a lower cutoff value yielded a higher kappa coefficient at the almost very good level or very good level. In contrast, the number of patients in the nociceptive pain group who remained negative stayed consistent: 0.80 for the cutoff value of 11 and 0.84 for the cutoff value of 10. When using the original cutoff value, the kappa coefficient was at the same level as with the original LANSS (0.65),[7] although higher kappa coefficients were observed in the Turkish (0.84) and Spanish (0.70) LANSS versions.[9,10] Regardless of the lower ICC in the nociceptive pain group, there was a good level of agreement of the LANSS-J screening results between the two assessments. Thus, the diagnostic utility with regard to agreement in the LANSS-J screening results was determined to be reasonably good. A large sample size, however, is needed for further assessment.

There are several limitations in the present study. First, generalization of the results of the present study is limited due to the relatively small sample size collected at a single institution. We prioritized patient recruitment with accurate diagnosis, and its feasibility as accurate diagnosis is essential in diagnostic utility. Thus, the findings should be considered exploratory in nature due to the limited number of the sample size. Our sample size may have resulted in lower sensitivity using the original cutoff value of 12. However, it should be kept in mind that the result may have resulted from the inclusion of patients with severe traumatic nerve injury in the sample. In addition, recruitment was conducted in a university hospital setting. As patients visiting a university hospital may differ from those receiving nonspecialized primary care, a particular group of patients were underrepresented. Further investigations with a large sample in various settings may be needed for more generic features of the LANSS-J, especially for nonspecialized primary care settings. For these limitations on generalizability, results need to be interpreted with care. Second, patients with neuropathic pain and those with nociceptive pain were recruited separately from the Department of Anesthesiology and Pain Relief Center and the Department of Orthopaedic Surgery and Spinal Surgery for feasibility reasons. Although the investigators administered LANSS-J in an interview format, the fact that not a single investigator assessed patients with both types of pain might have influenced the results to some extent. Results may differ if the LANSS-J is administered to patients experiencing pain of unknown origin at a nonspecialist, primary care level. Third, a partially stretched out paper clip was used to test for altered PPT to avoid skin cuts and bleeding because concerns were raised about using a 23-gauge needle for the pinprick (as the original LANSS Pain Scale instructed).[23] Patients' responses toward an altered PPT may differ if a needle were utilized in the present study (although pinprick has been commonly performed with a paper clip as an alternative method worldwide). Finally, to evaluate agreement in the LANSS-J assessments, we included only data that were obtained on the same day to retain the same evaluation time period in "as stable a condition as possible" by the primary and secondary investigators deemed to be equally capable of assessing patient conditions. It should be noted, however, that conducting the same-day assessment of the LANSS-J may not guarantee the same conditions for the two assessments regardless of a good level of agreement in the LANSS-J screening results based on kappa coefficients in patients whose assessments were conducted on the same day.

CONCLUSION

The present study indicated a sufficient level of diagnostic utility for the LANSS-J, demonstrating that the Japanese version of the LANSS Pain Scale is a valid screening tool for detecting pain originating from a neuropathic mechanism. The results suggest that employing the original cutoff value of 12 provides high specificity, allowing it to filter out patients with non-neuropathic pain. A lower cutoff value of 11 or 10 (which maintains the high specificity) may be more beneficial when evaluating Japanese patients whose pain was suspected to be caused by a neuropathic mechanism.

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DISCLOSURES

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ORIGINAL ARTICLE

Fear-avoidance beliefs are independently associated with the prevalence of chronic pain in Japanese workers

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Abstract

Purpose Pain is a global public health problem with implications for both personal and social heath. Fear-avoidance beliefs (FABs) have been demonstrated to negatively impact and prolong pain in many Western countries, but little is known about the association between FABs and chronic pain (CP) in Asian countries, including Japan. We examined the relationship between FABs and CP in Japanese white-collar workers, a growing population with a high prevalence of CP.

Methods Questionnaires and company records were used to gather data from 433 Japanese white-collar workers. Data were related to experience of pain, participant sociodemographic/health/lifestyle characteristics, fear-avoidance beliefs [Tampa Scale for Kinesiophobia (TSK)], work-related psychosocial factors (Brief Job Stress Questionnaire), and depressive illness [Psychological Distress Scale (K6)]. Analysis of covariance and multilevel logistic regression modeling were used to analyze associations between the data while controlling for factors known to influence CP prevalence.

Results Prevalence rate of CP was 11.1% (48 of 433 persons). Adjusted odds ratios for participants with CP significantly increased in participants with high TSK scores, even after adjusting for factors known to influence CP prevalence.

Conclusion We found a significant association between high TSK scores and CP in Japanese white-collar workers when controlling for other known factors that influence CP such as work-related psychosocial characteristics and depressive conditions. This finding suggests that FABs are independently associated with prevalence of CP.

Keywords Chronic pain · Fear of movement · Fear-avoidance belief · TSK · White-collar workers · Occupational medicine

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Introduction

Pain is a health problem that dramatically effects the global population [1, 2]. In particular, chronic pain (CP) can impair the daily lives of its sufferers, as well as placing a substantial economic burden on a country's resources [3]. A number of large-scale surveys suggest that CP is prevalent in approximately 20–25% of the Japanese population [4, 5], with prevalence differing between different work-related occupations [6]. For example, prevalence of chronic musculoskeletal pain is typically higher within "white-collar" professional, office, and technical employees, despite lower levels of demanding physical tasks. In contrast, employees within the "blue-collar" agricultural, forestry, and fisheries industries report lower rates of such chronic pain [6].

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To be able to prevent CP in white-collar workers (WCWs) would have substantial benefits in the lives of individuals who experience pain in their everyday lives. Furthermore, preventing CP effectively would also have economic and social benefits because of the association between CP and employment sick leave, absence, and poor productivity [7, 8]. The urgency to develop effective treatments and prevention strategies for CP is becoming increasingly more salient as there is a growing number of WCWs in the workforce [9], which thus increases the number of individuals experiencing CP.

Biological disorders are often considered as the primary causal factor for CP; however, it is also important to consider the effect of psychological and social factors, such as work-related stress and depression. In particular, dysfunctional beliefs relating to pain itself, and fear of pain, play a key role in the development of CP [10, 11]. Fear of pain can lead to avoidance of activities that patients associate with the occurrence or exacerbation of pain, even after physical recovery from the associated condition has occurred. The avoidance of physical activities based on fear of movement, known as kinesophobia, can also lead to a cycle of further fear and avoidance [12]. Moreover, excessive avoidance of activities believed to cause pain can reduce muscle strength and flexibility, which may delay recovery from a painful condition. This cycle of pain and avoidance behavior can be explained by a fear-avoidance model in which fear-avoidance beliefs (FABs) represent typical cognitive and emotional responses that can lead people with pain into a cycle of avoidance. Research has demonstrated that FABs contribute to long-term work-related disabilities; furthermore, low levels of FABs are a useful predictor of early recovery from an impairment [13, 14].

Although a number of studies in the United States and Europe have investigated the relationship between FABs and CP, very little research of a similar nature has taken place in Asian countries, including Japan. As the influence of FABs differs depending on culture and ethnicity [15], it is not possible to generalize the results from studies in Western populations to an Asian population. Our study aims to address this issue by investigating the prevalence of CP among Japanese WCWs, and furthermore, by analyzing the association between FABs and CP.

Methods

Data were collected from WCWs in the technology development division of a company listed on the First Section of the Tokyo Stock Exchange. Questionnaires were used to collect data relating to participants' pain, fear of pain, work-related psychosocial factors, and depression. We also collected data relating to participant demographics and lifestyle from the company's most recent employee health survey conducted within the year preceding the current study. The questionnaires were distributed to participants on February 10, 2015, and the survey was closed on February 29, 2015.

All procedures were approved by both the Keio University School of Medicine Ethics Committee (approval no. 20140296) and the Health and Safety Committee within the participating company. Participants were informed about the nature of the survey, and the use of demographic data from the annual health check, through the company's intranet.

Participants

In total, 517 full-time employees were asked to take part, with 433 returning completed questionnaires (83.8% response rate). Respondents were aged from 20 to 65 years old (mean = 41.5; standard deviation = 10.8). Male participants comprised the majority of the sample (375 participants, 86.8%). According to the company's data, all participants were recognized as WCWs who were engaged predominantly in deskwork.

Measures

Data were collected from the company's health check related to the participant's age, sex, body mass index (BMI, kg/m^2; participants categorized in quartiles), height, smoking habit (participants categorized as never, ex-smoker, or current smoker), daily alcohol intake [1 glass of sake (180 ml) was coded as 23 g ethanol; participants were categorized as consuming 0, 1–23, 24–45, or $\geq$46 g ethanol/day], highest education achieved (high school graduate or junior college graduate, bachelor's degree, master's degree, or doctorate), exercise routine, and daily working hours. Sleep patterns were evaluated for quantity of sleep in the past 4 weeks (participants categorized as having <5, 5, 6, 7, 8, 9, or >9 h/day) [16], with a reported sleep duration of less than 5 h coded as 'short sleep.' A measurement of participants' subjective evaluation of their exercise routine was also collected and used in the subsequent analyses.

Participants were asked to provide specific details of pain they had experienced during the previous 4 weeks relating to pain location(s), intensity, duration, and frequency. Location of pain was marked on an illustration by the participants (see Fig. 1), with multiple answers allowed. Pain intensity was scored on a numeric rating scale (NRS) comprising 11 points (0 = no pain to 10 = worst pain imaginable). Participants were coded as having CP when the following criteria were met: (1) NRS score of 5 or more, (2) pain persisted for at least 3 months, and (3) pain experienced at least two times a week [17].

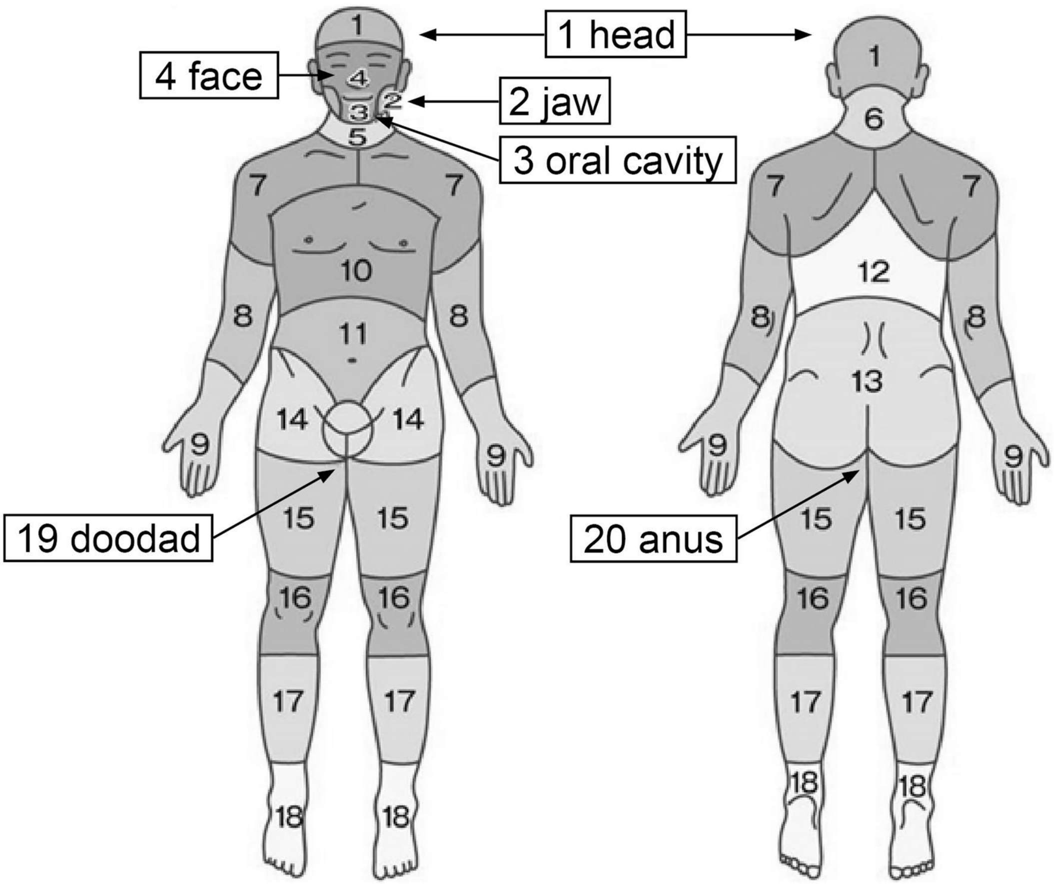

Fig. 1 Full-body manikin divided into 20 areas for marking of pain sites. Shoulder, back neck, low back, and head were defined as areas numbered *7*, *6*, *13*, and *1*, respectively

To evaluate kinesophobia within participants, we used the Japanese short version of the Tampa Scale of Kinesophobia (TSK-J11) developed and validated by Matsudaira et al. [18, 19]. Although a longer version of the TSK is available, we deemed the short version suitable for the study because of its good psychometric properties (Cronbach's $\alpha = 0.92$) and the advantage of brevity it offered [18, 20]. Reliability and validity of the TSK has been confirmed in several patient populations, including patients with chronic musculoskeletal pain [21], low back pain [22, 23], whiplash injury pain [24], shoulder pain [25], temporomandibular disorder [26], sciatica [27], and fibromyalgia [28]. The TSK-J11 comprises 11 items with each scored on a 4-point Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree). The total score is obtained by summing the scores for the 11 items and ranges from 11 to 44. Higher scores indicate a greater degree of kinesophobia within participants.

Work-related psychosocial factors were measured in five different aspects (job demand, job control, social support from supervisors and co-workers, and job satisfaction) using subscales of the Brief Job Stress Questionnaire (BJSQ) [29]. All items, except job satisfaction, were respectively rated on a 4-point Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree). Job demand was calculated by summing the item scores for psychological job overload within the BJSQ (three items). Job control was calculated by summing the item scores for subjective adjustability of work within the BJSQ (three items). The questionnaire section on social support from supervisors and co-workers consisted of three items, respectively, with the total score calculated by summing the three items, and ranging from 3 to 12 (lower scores indicating greater levels of support). Job satisfaction was rated on a 4-point scale ranging from 1 (satisfied) to 4 (unsatisfied).

Depressive condition was measured using the Kessler Psychological Distress Scale (K6). The Japanese version was developed in 2008, and then reliability and validity were confirmed by Furukawa et al. (Cronbach's α was 0.85) [30]. The K6 was developed in 2002 as a short-form version of the K10 [31] and consists of six items related to depression and anxiety, with each rated on a 5-point scale. In accordance with Kawakami, participants with a K6 score of 10 points or more were defined as having a depressive condition.

Statistical analysis

An analysis of Dunnett's test was conducted to test for differences in the age- and sex-adjusted means and proportions of participants' demographic and lifestyle characteristics. To investigate any association between kinesophobia and chronic pain, logistic regression was conducted to calculate multivariable-adjusted odds ratios (ORs) and 95% confidence intervals (95% CI). The data were fitted to three different regression models, with each adjusting for increasing numbers of variables. Model 1 adjusted for age, sex, BMI, smoking status, daily alcohol intake, highest education achieved, exercise habit, sleeping time, and working time. Model 2 also adjusted for job demands (categorized in tertiles), job control (categorized in tertiles), social support from supervisors and co-workers (categorized in quartiles), and job satisfaction (four categories) in addition to the control variables of model 1. Model 3 adjusted for depressive condition (K6 score ≥10) in addition to the control variables of model 2.

p values <0.05 for two-tailed tests were considered statistically significant. All statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC, USA).

Results

A total of 259 participants (60.0%) reported experiencing pain during the 4 weeks preceding the study, with 48 participants (11.1%) meeting the criteria for experiencing CP. The 211 participants who reported experiencing no pain in the previous 4 weeks were categorized into a non-CP group. The most frequently reported location of CP was in the shoulders (64.6%), followed by the back of the neck (54.2%), the low back (41.7%), and the head (31.3%).

Table 1 shows demographic characteristics of both the CP group and the non-CP group. Although no significant differences were observed between the groups for any of the items, there was a trend for higher BMI, poorer job control, poorer job satisfaction, and a higher rate of depressive people within the CP group when compared with the non-CP group.

Characteristics of participants who reported pain according to five categories of TSK-J11 scores are reported in Table 2. They were classified in quintiles as extremely low (Q1, 11–18), low (Q2, 19–20), intermediate (Q3, 21–23), high (Q4, 24–25), or extremely high (Q5, 26–44). Higher TSK-J11 scores were significantly associated with a greater prevalence of CP. In addition, a greater proportion of participants with high TSK-J11 scores reported poorer job control, poorer support from supervisors and co-workers, poorer job satisfaction, and a higher rate of depressive conditions (K6 score ≥10).

Table 1 Age- and sex-adjusted mean values and proportions of chronic pain risk factors

	Non-chronic pain	Chronic pain
n	211	48
Age, years (SE)	42.0 (0.7)	44.5 (1.5)
Men, *n*, %	185, 87.7%	40, 83.3%
Body mass index ≥25, *n*, %	42, 19.9%	12, 25.0%
Current smoker, *n*, %	15, 7.1%	4, 8.3%
Alcohol intake >46 g/day, *n*, %	32, 15.2%	9, 18.8%
Master's degree, *n*, %	156, 73.9%	37, 77.1%
Exercise >30 min twice a week, *n*, %	141, 66.8%	29, 60.4%
Sleep time 5 h or less, *n*, %	11, 5.2%	3, 6.3%
Working time ≥10 h, *n*, %	117, 55.5%	25, 52.1%
High job demands, *n*, %	66, 31.3%	17, 35.4%
Poor job control, *n*, %	71, 33.7%	23, 47.9%
Poor support from supervisor, *n*, %	65, 30.8%	16, 33.3%
Poor support from co-workers, *n*, %	59, 28.0%	11, 22.9%
Job dissatisfaction, *n*, %	51, 24.2%	15, 31.3%
K6 ≥10 points, *n*, %	11, 5.2%	4, 8.3%

No significant differences were observed between the groups for any of the items

SE standard error, *K6* Kessler Psychological Distress Scale

Table 3 illustrates the age- and sex-adjusted OR values for the CP versus non-CP groups according to TSK score. Significantly higher age- and sex-adjusted OR values of CP versus non-CP were observed among participants with extremely high TSK scores (Q5) compared to the participants with extremely low TSK scores. The OR values gradually increased for participants in the Q5 groups (3.13). In the first model, which adjusted for additional demographics and lifestyle variables, the Q5 group also exhibited significantly high OR values (3.13), with the difference remaining significant after adjusting for both the work-related psychosocial variables in model 2 (OR = 4.07) and the depressive symptom variables in model 3 (OR = 4.09). The stepwise increase in OR values with TSK score found in the columns of Q4 and Q5 also remained in all the models.

Table 2 Age- and sex-adjusted mean values and proportions of chronic pain risk factors according to the Tampa Scale for Kinesiophobia

	Tampa Scale for Kinesiophobia (TSK)				
	Q1 TSK = 11–18	Q2 TSK = 19–20	Q3 TSK = 21–23	Q4 TSK = 24–25	Q5 TSK = 26–44
n	52	37	61	38	63
Age, years (SE)	41.7 (1.5)	40.6 (1.7)	41.7(1.4)	44.2 (1.7)	43.9(1.3)
Men, *n*, %	42, 80.8%	31, 83.8%	51, 83.6%	36, 94.7%	57, 90.5%
Body mass index ≥ 25, *n*, %	11, 21.2%	5, 13.5%	14, 23.0%	6, 15.8%	16, 25.4%
Current smoker, *n*, %	2, 3.8%	4 10.8%	3, 4.9%	4, 10.5%	6, 9.5%
Alcohol intake more than 46 g/day, *n*, %	9, 17.3%	2, 5.4%	6, 9.8%	7, 18.4%	13, 20.6%
Master's degree, *n*, %	39, 75.0%	28, 75.7%	43, 70.5%	26, 68.4%	50, 79.4%
Exercise >30 min twice a week, *n*, %	38, 73.1%	21, 56.8%	44, 72.1%	30, 78.9%	33, 52.4%*
Sleep time 5 h or less, *n*, %	2, 3.8%	1, 2.7%	3, 4.9%	3, 7.9%	8, 12.7%
Working time ≥10 h, *n* (%)	33, 63.5%	20, 54.1%	35, 57.4%	23, 60.5%	27, 42.9%*
High job demands, *n*, %	24, 46.2%	9, 24.3%	17, 27.9%	12, 31.6%	17, 27.0%
Poor job control, *n*, %	8, 15.4%	16, 43.2%*	21, 34.4%	15, 39.5%*	32, 50.8%‡
Poor support from supervisor, *n*, %	9, 17.3%	14, 37.8%	13, 21.3%	15, 39.5%	28, 44.4%‡
Poor support from co-worker, *n*, %	9, 17.3%	6, 16.2%	18, 29.5%	10, 26.3%	24, 38.1%*
Job dissatisfaction, *n*, %	7, 13.5%	5, 13.5%	15, 24.6%	12, 31.6%	25, 39.7%†
K6 ≥10 points, *n*, %	3, 5.8%	4, 10.8%	10, 16.4%	7, 18.4%	15, 23.8%†
Chronic pain, *n*, %	6, 11.5%	4, 10.8%	6, 9.8%	10, 26.3%	20, 31.7%*

Test for significance from the category of Q1: * $p < 0.05$, † $p < 0.01$, ‡ $p < 0.001$

SE standard errors

Table 3 Odds ratios (ORs, 95% CI) of chronic pain versus non-chronic pain according to Tampa Scale for Kinesiophobia

	Tampa scale for kinesiophobia: TSK				
	Q1 TSK = 11–18	Q2 TSK = 19–20	Q3 TSK = 21–23	Q4 TSK = 24–25	Q5 TSK = 26–44
No. of subjects	52	37	61	38	63
No. of subjects with chronic pain	6	4	6	10	20
Age-adjusted mean values	1.00	0.80 (0.22–2.89)	0.70 (0.23–2.17)	2.43 (0.85–7.00)	3.09 (1.22–7.82)*
Model 1 OR (95% CI)	1.00	0.73 (0.18–2.89)	0.68 (0.21–2.20)	2.46 (0.82–7.42)	3.13 (1.17–8.37)*
Model 2 OR (95% CI)	1.00	0.76 (0.18–3.26)	0.65 (0.19–2.26)	2.73 (0.81–9.19)	4.07 (1.35–12.23)*
Model 3 OR (95% CI)	1.00	0.79 (0.18–3.40)	0.64 (0.18–2.22)	2.66 (0.79–8.98)	4.09 (1.35–12.42)*

Test for significance from the category of Q1: * $p < 0.05$, † $p < 0.01$, ‡ $p < 0.001$

SE standard error

Discussion

This is the first study demonstrating that kinesophobia adversely affects CP in Japanese employees. Because the biopsychosocial model makes a substantial contribution in explaining the complicated mechanisms that underpin CP [32], psychosocial factors should also be taken into account to identify the independent relationship between kinesophobia and CP. As such, we performed multiple logistic regression analyses controlling biological characteristics, work-related factors (psychosocial factors), and depression (psychological factor).

In model 1, we adjusted for demographic and lifestyle factors comprising age, sex, BMI, smoking status, daily alcohol intake, highest education achieved, exercise routine, sleeping time, and working time. Although exercise routine indicates low pain sensitivity [8, 33], high TSK scores were significantly associated with higher prevalence of CP, even after adjusting for factors including exercise. Although an exercise routine may alleviate kinesophobia and improve TSK score, the influence was statistically low in the present study.

In model 2, we investigated the effect of psychosocial factors on the relationship between kinesophobia and CP.

The demand-control model posits “high strain jobs” [jobs that combine high demand within a job and low job control (low decision latitude)] as having adverse effects on employees’ health [34]. Furthermore, social support by supervisors and co-workers is argued to also be an influential psychosocial factor in the workplace [34], with the demand-control-support model suggesting that workplace support (as well as job control) can reduce a job stress induced by job demand. Another influential psychosocial factor is job satisfaction, referring to the overall well-being an employee feels toward their job [35]. Conversely, job dissatisfaction refers to the negative emotions elicited through a reciprocal deficit in effort-reward, illustrated in the imbalance model [36]. A number of studies have highlighted the importance of these factors, with poor work-related psychosocial factors associated with a higher prevalence of CP among European and North American employees [37–39], and job satisfaction significantly associated with CP in Japanese employees [40–42]. As such, we adjusted for work-related psychosocial factors in model 2 of the current study. The results indicated that, even after adjusting for work-related psychosocial factors, OR values for participants with extremely high TSK scores remained significant, suggesting that FABs influenced the prevalence of CP independently of the psychosocial factors.

In model 3, we also adjusted for depressive condition because previous research has demonstrated depression as an independent factor that adversely affects CP [42]. Job stress is also an indicator of depression [42]. As in model 2, the OR values in model 3 for participants with extremely high TSK scores remained significantly high after adjusting for depression, further supporting the view that kinesophobia is an independent risk factor of CP.

The prevalence of FABs in acute, or subacute, phases of painful conditions can prolong pain and lead to intractable conditions [43, 44]. As shown in this study, the independent association between FABs and the prevalence of CP suggests the similar negative impact of FABs on pain. Therefore, tackling FABs is an important therapeutic approach for reducing CP. The introduction of a psychosocial flag system for chronic musculoskeletal pain is one such approach and is strongly recommended in Europe and the United States. Under this system, FABs indicate a yellow flag, which requires the employee to receive treatment from clinical physicians working in collaboration with the workplace [45]. To effectively contend with CP, it is necessary for Japanese physicians to understand the complex nature of occupational health and CP and provide interventions that target pain in the earliest stages of onset.

There were a number of limitations in the current study. First, it is likely that selection bias influenced the results to some degree. The fact that the participating company positively accepted to take part in the study perhaps suggests that they have a strong interest in occupational health. However, even within a company that supports its employee’s health, the present study demonstrated that more than one tenth of their employees suffered from severe chronic pain and FABs associated with CP. Unfortunately, it was impossible to infer the degree to which selection bias may have impacted the results because of the lack of other research focusing on the relationship between CP and occupational environments in Japan. More investigations will be expected to identify risk factors of CP in the work site. Second, data relating to the cause of pain were not collected. It is possible that classifications of pain may have influenced the present results; however, nociceptive and neuropathic pain classification of pain overlap in most patients who experience pain [46], which suggests that classifying pain in such a way is not necessary. Finally, because of the cross-sectional nature of the study, causality regarding the direction of influence between TSK and CP cannot be inferred. It is possible that long-lasting severe pain elevated TSK scores in participants who experienced pain. To clarify causality, future research should include panel data analysis.

In conclusion, we found a significant association between high TSK score and CP in Japanese white-collar workers when controlling for other known factors that influence CP, such as work-related psychosocial characteristics and depressive conditions. This result suggests that FABs are independently associated with the prevalence of CP.

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Compliance with ethical standards

Conflict of interest The authors have no conflicts of interest to declare.

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ORIGINAL RESEARCH

Estimated risk for chronic pain determined using the generic STarT Back 5-item screening tool

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Objective: The generic STarT Back 5-item screening tool (STarT-G) is used to manage chronic pain in the lower back and elsewhere. This study evaluated the validity of the Japanese version of this generic screening tool.

Materials and methods: Japanese participants between the ages of 20 and 64 years completed online surveys regarding pain. Survey reliability was assessed with internal consistency, as calculated using Cronbach's alpha coefficients. Spearman's correlation coefficients were used to evaluate concurrent validity between the STarT-G score and standard reference questionnaires. Associations between STarT-G scores and the presence of a disability due to chronic pain (DCP) were analyzed using receiver operator characteristic (ROC) curves.

Results: Analyses ultimately included data obtained from 52,842 Japanese participants (54.4% male) with a mean (standard deviation) age of 47.7 (9.4) years. Approximately 1.5% of participants had DCP, and the mean STarT-G score was 1.2 (1.4). The Cronbach's alpha coefficient was 0.71, indicating an acceptable reliability. The STarT-G score moderately correlated with the pain numerical rating scale (NRS) score (Spearman's correlation coefficient: $r = 0.34$). When the STarT-G threshold was set at 4, the sensitivity and specificity of the DCP predictive model were 65.8% and 82.4%, respectively, and the area under the ROC was 0.808.

Conclusion: The STarT-G was internally consistent and was able to distinguish between subjects with and without a DCP. Therefore, the STarT-G can reliably be used in the Japanese population to identify patients with DCP.

Keywords: chronic pain, disability, primary care, psychological factors, screening tool, somatic symptoms

Introduction

Disability due to chronic pain (DCP) results in absence from work and is a major public health concern in Japan and many Western countries.[1–4] Various screening tools have been developed to identify chronic pain subgroups and comorbid factors.[5–7] A widely used powerful tool is the STarT Back Tool (STarT), a 9-item screening tool that was developed as a prognostic indicator of lower back pain (LBP). Items 1–4 evaluate physical factors and items 5–9 assess psychosocial factors (Figure 1).[5,8] The STarT score is often used by primary care physicians in England to make clinical decisions.[5] Specifically, the STarT results indicate the subgroup that an LBP patient falls into, which helps determine which treatment strategies may be most effective. The STarT has been shown to be particularly effective for individual patient management in the physiotherapy setting. Patients who underwent STarT testing and subsequent targeted therapy had higher clinical and cost efficacy than patients who did not undergo STarT

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Patient name: ______________________________ Date: ____________

Thinking about the **last 2 weeks** tick your response to the following questions:

		Disagree 0	Agree 1
1	My back pain has **spread down my leg(s)** at some time in the last 2 weeks	☐	☐
2	I have had pain in the **shoulder** or **neck** at some time in the last 2 weeks	☐	☐
3	I have only **walked short distances** because of my back pain	☐	☐
4	In the last 2 weeks, I have **dressed more slowly** than usual because of back pain	☐	☐
5	It's not really safe for a person with a condition like mine to be physically active	☐	☐
6	**Worrying thoughts** have been going through my mind a lot of the time	☐	☐
7	I feel that **my back pain is terrible** and **it's never going to get any better**	☐	☐
8	In general I have **not enjoyed** all the things I used to enjoy	☐	☐

9. Overall, how **bothersome** has your back pain been in the **last 2 weeks**?

Not at all	Slightly	Moderately	Very much	Extremely
☐	☐	☐	☐	☐
0	0	0	1	1

Total score (all 9): _________________ Sub Score (Q5-9):_____________

Figure 1 The Keele STarT Back screening tool (9-item).
Note: Copyright ©2007. Reprinted from Keele University. STarT Back Screening Tool Website. Available from: https://www.keele.ac.uk/sbst/startbacktool/usingandscoring/.[8]

testing and were treated with usual care strategies.[5] We previously translated the STarT into Japanese,[9] and this version was linguistically validated in a general cross-cultural adaptation process.[10–12] We also evaluated the reliability and validity of "the STarT into Japanese" in a large number of Japanese patients with LBP.[13]

The lower back was the most common site of chronic pain and accounted for 65% of all cases of reported chronic pain in a Japanese epidemiological study.[1] However, chronic pain often originates in places other than the lower back, and a generic screening tool is needed to help effectively manage chronic pain from all sites. One such tool is the generic version of the STarT Back 5-item screening tool (STarT-G), a modified version of the 9-item STarT.[8] The STarT 9-item screening tool provides an easy way to stratify patients into three subgroups according to the probability of a poor prognosis or pain chronicity. These categories are defined as "low risk," "medium risk," and "high risk" (Figure 2).[8] On the other hand, the use of STarT-G (5-item) screening tool has not yet been established. The STarT-G has also not been validated for evaluating chronic pain in a large group of Japanese subjects. Therefore, the current study was performed to examine the validity of STarT-G in such a population using cross-sectional data obtained from STarT-G surveys administered online.

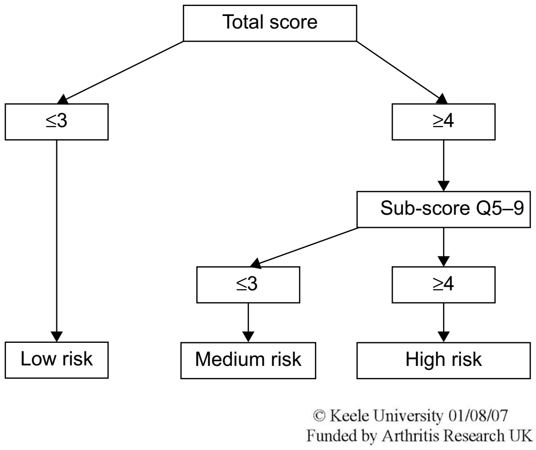

Figure 2 The STarT Back tool scoring system.
Notes: Scores were used to stratify patients into "low risk," "medium risk," and "high risk" groups. Copyright ©2007. Reprinted from Keele University. STarT Back Screening Tool Website. Available from: https://www.keele.ac.uk/sbst/startbacktool/usingandscoring/.[8]

Materials and methods

This study was reviewed and approved by the medical/ethics review board of the Japan Labour Health and Welfare Organization at Kanto Rosai Hospital (Kanagawa, Japan, approval number: 2012-22). All study procedures adhered to the tenets of the Declaration of Helsinki. Participation was voluntary, and no personal information was collected. Written informed consent was not obtained, but submitting the completed questionnaire was considered evidence of consent. Before completing the questionnaire, potential participants read an explanation of the survey's purpose and were informed that they should proceed to the questionnaire only if they agreed to participate in the study. As an incentive, participants received online shopping reward points from the Internet research company that helped conduct this study (UNITED, Inc., Tokyo, Japan).

Study population

Subject information was collected via surveys administered online in January and February 2014. Participants were recruited from an online panel conducted by an Internet research company (UNITED, Inc.). The all-Japanese study population consisted of ~1.25 million registered research volunteers between the ages of 20 and 64 years. From this volunteer pool, 965,919 individuals were randomly selected and invited by e-mail to complete an online questionnaire on health problems associated with pain. We ultimately obtained 52,842 online responses by January 31, 2014.

Study measures

The 5-item STarT-G tool is a modified version of the 9-item psychosocial subscale that specifically identifies distress in other conditions.[5] Questions address fear (one item from the Tampa Scale of Kinesiophobia), anxiety (one item from the Hospital Anxiety and Depression Scale), pessimistic patient expectations (one item from the Pain Catastrophizing Scale), low mood, (one item from the Hospital Anxiety and Depression Scale), and how bothersome pain is.[7] The first four items had possible responses of "agree" or "disagree," and the bothersome item had possible responses from 0 to 5 (Likert scale). We used the 5-item STarT back screening tool that is available from the Keele University website (March 2013, Figure 3).[8]

The study questionnaire investigated pain experienced over the past month in 20 different anatomical sites. All anatomical sites were illustrated on diagrams to ensure that participants correctly identified each area. Examined sites included the head, chin, teeth/mouth, face, throat, neck, shoulder, elbow, wrist/hand, chest, abdomen, back, low back, hip, thigh, knee, lower leg, ankle/foot, genitals, and anus. The degree of chronic pain experienced over the last 4 weeks was assessed using the numerical rating scale (NRS), with scores ranging from 0 (no pain at all) to 10 (the worst pain imaginable).

Somatizing tendency was assessed using a subset of items from a linguistically validated Japanese version of the Brief Symptom Inventory (BSI).[14,15] Seven somatic symptoms were assessed for severity, including faintness or dizziness, pain in the heart or chest, nausea or upset stomach, difficulty breathing, numbness or tingling in part of the body, weakness in part of the body, and hot or cold spells. All symptoms were assessed on a five-point scale that evaluated how much the participant was bothered by the symptom. Participants chose from the following response options: not at all (0), mildly (1), moderately (2), quite a bit (3), and extremely (4). For this test, participants were grouped by the number of somatic symptoms or pain sites. A participant was considered to have a symptom if he/she responded with a 2–4, which is indicative of somatization.[16,17]

The presence/absence of a DCP was also investigated. A DCP was considered present when the pain symptoms had continued for at least 6 months and the subject had withdrawn from social activities because of pain.

Statistical analyses

Data are presented as mean (standard deviation), where applicable. Participant demographic and clinical characteristics were summarized using descriptive statistics. To examine floor and ceiling effects, the percentages of respondents with total scores of 0 and 5 were calculated. Floor and ceiling effects were considered present when >15% of respondents had the lowest or highest possible score, respectively.[18] To examine STarT-G reliability, we evaluated

Patient name: ______________________________ Date: ____________

Thinking about the **last 2 weeks** tick your response to the following questions:

		Disagree 0	Agree 1
1	It's really not safe for a person with a condition like mine to be physically active	☐	☐
2	**Worrying thoughts** have been going through my mind a lot of the time in the last 2 weeks	☐	☐
3	I feel that **my problem is terrible** and that **it's never going to get any better**	☐	☐
4	In general in the last 2 weeks, I have **not enjoyed** all the things I used to enjoy	☐	☐

5. Overall, how **bothersome** has your condition been in the last 2 weeks?

Not at all	Slightly	Moderately	Very much	Extremely
☐	☐	☐	☐	☐
0	0	0	1	1

Score______________

Figure 3 The generic condition screening tool (5-items).
Note: Copyright ©2007. Reprinted from Keele University. STarT Back Screening Tool Website. Available from: https://www.keele.ac.uk/sbst/startbacktool/usingandscoring/.[8]

internal consistency by calculating Cronbach's alpha coefficients. An alpha index >0.70 indicates a satisfactory internal consistency.[19] Spearman's correlation coefficients were used to evaluate concurrent validity by examining correlations between STarT-G and NRS pain scores. Correlation coefficients were interpreted using Cohen's[20] criteria for correlation strength in psychometric validation (0.10 = weak, 0.30 = moderate, and 0.50 = strong).

The ability of STarT-G scores to differentiate between participants with known differences (known-group validity) was examined using the Jonckheere–Terpstra test. To do this, participants were categorized into the following groups according to the number of somatic symptoms present: no symptoms, one symptom, and two or more symptoms.

Associations between STarT-G scores and the presence of a DCP were examined using receiver operator characteristic (ROC) curves and the corresponding area under the curve (AUC). Accuracy was determined using the AUC. The following traditional academic point system for AUC values can be used as a rough guide for classifying diagnostic test accuracy: 0.90–1.00 = excellent, 0.80–0.90 = good, 0.70–0.80 = fair, 0.60–0.70 = poor, and 0.50–0.60 = fail.[21] Statistical analyses were performed using SPSS statistical software (version 20.0; SPSS, Inc., Chicago, IL, USA). All reported P values are two-sided, and statistical significance was defined as $P < 0.05$.

Results

A total of 52,842 participants were ultimately included in analyses. Mean subject age was 47.7 (9.4) years, and 54.4% of participants were male. Approximately 1.5% of participants claimed to have experienced a DCP. Table 1 summarizes participant demographic characteristics and overall pain survey results.

Mean STarT-G score was 1.2 (1.4). A remarkable ceiling effect was not observed, with only 2.3% of participants reporting the highest score of 5. However, a substantial floor effect was observed, with 41.0% of participants reporting the lowest score of 0. The Cronbach's alpha coefficient was

Table 1 Participant demographic and pain characteristics

Characteristics	
Sex, n (%)	
Male	28,769 (54.4)
Female	24,073 (45.6)
Age, years	47.7 (9.4)
BMI, kg/m^2	22.8 (3.8)
STarT-G score	1.2 (1.4)
NRS for pain	3.1 (2.4)
Pain sites, n (%)	
0	12,045 (22.8)
1	14,076 (26.6)
2	10,014 (19.0)
3	6,370 (12.1)
4–5	6,188 (11.7)
6–9	3,484 (6.6)
10+	665 (1.3)
Disability due to chronic pain, n (%)	
Present	818 (1.5)
Absent	52,024 (98.5)

Note: Data presented as mean (standard deviation) where applicable.
Abbreviations: BMI, body mass index; STarT-G, generic version of the STarT Back 5-item screening tool; NRS, numerical rating scale.

0.71, indicating good test reliability. Concurrent validity was examined by investigating the correlation between STarT-G score and pain NRS. The two pain measures were only moderately correlated ($r = 0.34$).

We examined the STarT-G scores among participants with known differences. As expected, participants with more somatic symptoms had significantly higher STarT-G scores. The mean score was 0.97 (1.12), 1.96 (1.42), and 2.74 (1.53) in participants with zero, one, and two or more somatic symptoms, respectively (Figure 4). This linear trend of increasing total STarT-G score with an increasing number of somatic symptoms was highly significant (Jonckheere–Terpstra test, $P < 0.0001$). Furthermore, participants with pain at a higher number of body sites had significantly higher STarT-G scores. The mean score was 0.63 (1.05), 1.05 (1.25), 1.27 (1.30), 1.50 (1.37), 1.80 (1.45), 2.23 (1.54), and 2.96 (1.57) in participants with zero, one, two, three, four-to-five, six-to-nine, and ≥10 pain sites, respectively (Figure 5). This linearly increasing trend in STarT-G score with an increasing number of bodily pain sites was highly significant (Jonckheere–Terpstra test, $P < 0.0001$).

The ability of the model to predict the presence of a DCP was also examined when the STarT-G threshold was set to 4. At this cutoff value, sensitivity and specificity for detecting a DCP were 65.8% and 82.4%, respectively. Additionally, area under the ROC curve was 0.808 for this STarT-G threshold, indicating that the model was good (Figure 6).

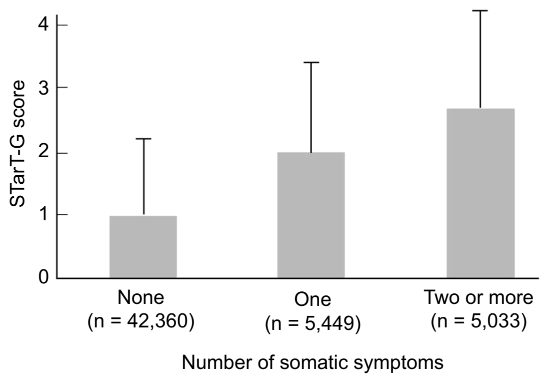

Figure 4 Mean STarT-G scores for participants with different numbers of somatic symptoms.
Notes: The linear trend was found to be highly significant (Jonckheere–Terpstra test, $P < 0.0001$). The STarT-G is the generic version of the STarT Back 5-item screening tool. The number of somatic symptoms was determined using the Brief Symptom Inventory somatization scale.

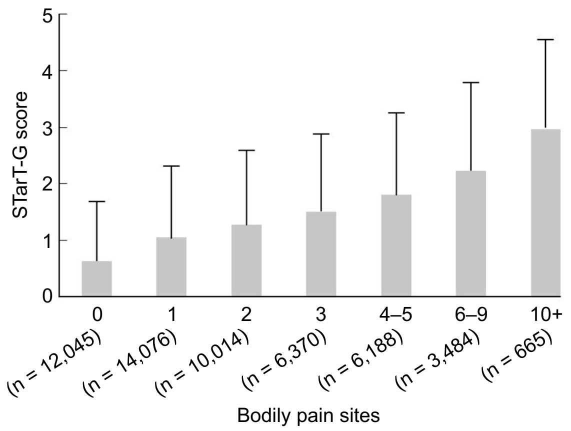

Figure 5 Mean STarT-G scores for participants with different numbers of pain sites.
Notes: The linear trend was found to be highly significant (Jonckheere–Terpstra test, $P < 0.0001$). The STarT-G is the generic versions of the STarT Back 5-item screening tool. The number of pain sites represents pain experienced during the past month in the head, chin, teeth/mouth, face, throat, neck, shoulder, elbow, wrist/hand, chest, abdomen, back, low back, hip, thigh, knee, lower leg, ankle/foot, genitals, and/or anus.

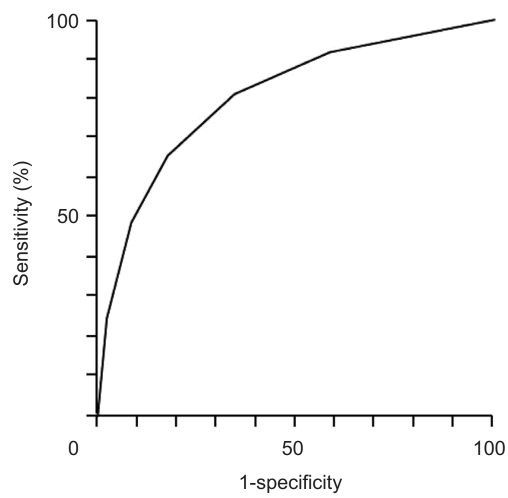

Figure 6 Receiver operating characteristics (ROC) curve of disability due to chronic pain, as assessed using a STarT-G score threshold value of 4.
Note: The area under the ROC curve was 0.808.

Discussion

Here, we evaluated psychometric properties of the STarT-G. We found that the survey was internally consistent and had acceptable concurrent and known-groups validity in the Japanese population. The Cronbach's alpha coefficient for the STarT-G was 0.71, indicating a good internal consistency. This value was similar to that obtained for the Japanese 9-item STarT scale (0.75).[13] Concurrent validity was assessed by analyzing correlations between the STarT-G and pain NRS scores, which were moderately correlated with each other ($r = 0.34$). Known-group validity was investigated by examining relationships between STarT-G scores and the number of somatic symptoms and body pain sites. These analyses showed that the STarT-G score increased as the number of somatic symptoms and pain sites increased. This suggests that the STarT-G is able to differentiate between patients with different levels of chronic pain and pain-related problems.

Yellow flags are useful in identifying patients with chronic LBP who have a poor prognosis.[22] The 5-item tool covers the minimal important psychological factors that are considered to be yellow flags for overall chronic LBP. This survey includes questions related to fear, anxiety, catastrophizing, depression, and bothersomeness, all of which are the most important predictors identified as yellow flags. For patients with high STarT-G scores, specific cognitive behavioral approaches are needed in addition to pain education, motivation, encouragement, exercise, medical therapy (minimal amounts), and physical treatment. This conclusion is based on previous reports that stated, "early intervention to yellow flag leads to better outcome."[23,24]

Finally, ~1.5% of participants reported having a DCP. At a STarT-G threshold value of 4 points, ROC analysis revealed that the sensitivity and specificity of DCP were 65.8% and 82.4%, respectively. Additionally, the AUC was 0.808, indicating a good capacity of the STarT-G to differentiate between patients with and without a DCP.

The STarT-G is a diagnosis-specific screening tool used for communication between primary care physicians and pain specialists in the care of chronic pain patients. Using the STarT-G threshold of 4 points, patients examined here were divided into the following two groups: those at risk for a DCP and those with minimal to no risk for a DCP. We recommend that patients at or beyond this threshold consult a pain specialist. The STarT-G is now planned to be used as a tool to identify patients for referral to one of 18 core facilities in Japan that provide cognitive behavioral therapy.

Our study had several limitations. First, our study population was selected from Internet research volunteers who have chronic pain. Given that 41% of participants had a STarT-G score of 0, many patients may have had chronic pain that was not severe enough to require medical care. This may have influenced our results. Second, Internet-based surveys can introduce a selection bias and may not be representative of the general population. Because our study population was selected from Internet research volunteers who may differ from general Internet users, caution is needed when interpreting our study findings. In particular, people living in large cities are overrepresented in Internet survey company volunteers. In addition, a higher proportion of respondents had completed university or graduate level education than the general population, particularly in older respondents.[25] Third, our study had a test reliability of >0.70.[19] However, Nunnally and Bernstein[26] recommend a minimum test reliability of >0.90 for making clinical decisions. Therefore, it is possible that test reliability was overestimated. Finally, this cross-sectional study did not assess the ability of the STarT-G to predict pain consistency. Future longitudinal studies are needed to better understand potential associations between risk groups and long-term pain outcomes. These should also examine whether or not the STarT-G score is predictive of DCP.

Conclusion

The STarT-G scale had acceptable internal consistency, reliability, and validity (concurrent and known groups) in Japanese patients with chronic pain. We hope that these analyses of the psychometric properties of STarT-G will enable Japanese clinicians to use this survey as a screening tool for detecting DCPs. The STarT-G is simple, fast, and suitable for use in primary care settings, all of which suggest that the STarT-G may facilitate screening for DCP in the primary care setting in Japan. We hope using the STarT-G will ultimately ease physical, social, and economical burdens of chronic pain in the Japanese population.

Disclosure

The authors report no conflicts of interest in this work.

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ORIGINAL RESEARCH

Sex-specific impact of early-life adversity on chronic pain: a large population-based study in Japan

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Background: Responses to early-life adversity may differ by sex. We investigated the sex-specific impact of early-life adversity on chronic pain, chronic multisite pain, and somatizing tendency with chronic pain.

Methods: We examined 4229 respondents aged 20–79 years who participated in the Pain Associated Cross-Sectional Epidemiological Survey in Japan. Outcomes were: 1) chronic pain prevalence, 2) multisite pain (≥3 sites) prevalence, and 3) multiple somatic symptoms (≥3 symptoms) among respondents with chronic pain related to the presence or absence of early-life adversity.

Multivariable-adjusted odds ratios (ORs) were calculated with 95% confidence intervals using a logistic regression model including age, smoking status, exercise routine, sleep time, body mass index, household expenditure, and the full distribution of scores on the Mental Health Inventory-5. We further adjusted for pain intensity when we analyzed the data for respondents with chronic pain.

Results: The prevalence of chronic pain was higher among respondents reporting the presence of early-life adversity compared with those reporting its absence, with multivariable ORs of 1.62 (1.22–2.15, $p<0.01$) in men and 1.47 (1.13–1.90, $p<0.01$) in women. Among women with chronic pain, early-life adversity was associated with multisite pain and multiple somatic symptoms; multivariable ORs were 1.78 (1.22–2.60, $p<0.01$) for multisite pain and 1.89 (1.27–2.83, $p<0.01$) for ≥3 somatic symptoms. No associations were observed between early-life adversity and chronic multisite pain or multiple somatic symptoms among men with chronic pain.

Conclusion: Early-life adversity may be linked to a higher prevalence of chronic pain among both sexes and to multisite pain and somatizing tendency among women with chronic pain.

Keywords: sex characteristics, early-life adversity, chronic pain, somatoform disorders, disaster

Introduction

Early-life adversity (ELA) is defined as traumatic experiences during childhood encompassing maltreatment, accidents, death of a close relative, and disaster, any of which could have an influence not only in childhood but also in later life in the form of difficulties such as posttraumatic stress disorder (PTSD) or irritable bowel syndrome.[1,2] Previous studies have also described the relationship between ELA events and chronic pain (e.g., low back pain or fibromyalgia), but most of these studies were small-scale or targeted to North American, European, Oceanian populations,[3–7] and once targeted to Japanese population.[8]

This study focuses on the effects of ELA as a broader concept in relation to chronic pain. We used a question about adverse life events in general, rather than specific adversities.

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Various sex or gender differences in tolerance for stressful life events have been documented. For example, a meta-analytic review revealed that women reported more symptoms of depression and anxiety than did men, but that the sex difference in psychological symptoms accounted for only about 4% of the variance in sex differences in reports of stress.[9] Sex or gender differences as they relate to chronic pain have been discussed for decades. The prevalence of chronic pain among women is higher than that among men,[10,11] and somatic symptoms have been reported by women than by men.[12,13]

We hypothesized that ELA would have long-term adverse impact, which manifested as chronic pain on more women than men, so we investigated the sex-specific association between ELA and the prevalence of chronic pain, chronic multisite pain, and somatizing tendency complicated by chronic pain in a large population-based study of Japanese men and women aged 20–79 years.

Methods

Ethical provisions

All procedures followed were in accordance with the ethical standards of the Helsinki Declaration of 1975 as revised in 2000. The institutional review boards of Keio University and of the Japan Labour Health and Welfare Organization approved this study. All participants had given their written informed consent before responding to the questionnaire. A credit point for Internet shopping was given as an incentive to the respondents.

Study population

The Pain Associated Cross-Sectional Epidemiological (PACE) study was a web-based survey designed to evaluate pain in a large Japanese population using a self-reported questionnaire. The PACE survey was conducted from 10 to 18 January 2009. The data set was the same as in previous PACE studies, profiles of which have been reported elsewhere;[14,15] however, the aim of this study was completely different from that of previous studies. Figure 1 shows the sampling procedure that culminated in the sample analyzed in the present study. A total of 20,044 respondents (9,746 men and 10,298 women) aged 20–79 years and matching the Japanese demographic composition in 2007 (Japanese Ministry of Internal Affairs and Communications, 2007) were recruited by e-mail from 1,477,585 candidates who registered with an Internet survey company (Rakuten Research, Inc., Tokyo, Japan). Computer-generated invitational e-mails were sent with a link to the first questionnaire until the targeted sample number was achieved. Incomplete questionnaires were rejected automatically, so the response rate was not calculated. The first questionnaire included items on age, sex, and pain, and was completed by 20,044 respondents. Subsequently, detailed questionnaires about lifestyle and psychosocial factors were sent to 5,000 of these respondents. Half (2,500) were chosen from those who had reported pain on the first questionnaire; the other half had reported being pain-free. The profile of these 5,000 respondents was consistent with the Japanese demographic composition for sex and age in 2007.[16] A total of 5,000 participants responded to the second questionnaire. Of these, we drew the data on 4,229 individuals (1,729 with chronic pain and 2,500 without pain) in the analyses. Moreover, the respondents with chronic pain were included in some additional analyses.

Definitions and measures

Chronic pain

The first questionnaire included items on pain such as the pain sites, pain intensity at each site, the site of dominant pain, and the duration of dominant pain. Pain intensities were scored on an 11-point Numerical Rating Scale (NRS; 0=no pain, 10=worst pain imaginable). In accord with the definition of chronic pain from the International Association for the Study of Pain, participants reported persistent pain over 3 months.[17]

Early-life adversity

We used a simple yes/no question to detect ELA, “Did you have any mentally shocking events (e.g., accidents experienced by you or close relatives, death of close relatives or friends, disaster, injury from violence) when you were 14 years old or younger?”.

Multisite pain

The questionnaire included a picture of a human form with its body parts numbered from 1 to 21, and respondents entered the number(s) that corresponded to their pain site(s). A count of pain sites is a simple and useful measure for the severity of chronic pain, and chronic multisite pain is a strong predictor of future disability.[18] We defined more than three pain sites as multisite pain in the current study.

Somatizing tendency

Somatic symptom disorder involves having physical symptoms such as fatigue or dizziness caused by major emotional distress and problems functioning.[19] The disorder decreases its sufferers’ quality of life. The Brief Symptom Inventory (BSI) is a self-reported measure of somatic symptoms, in which respondents answer on a 5-point Likert-type scale,

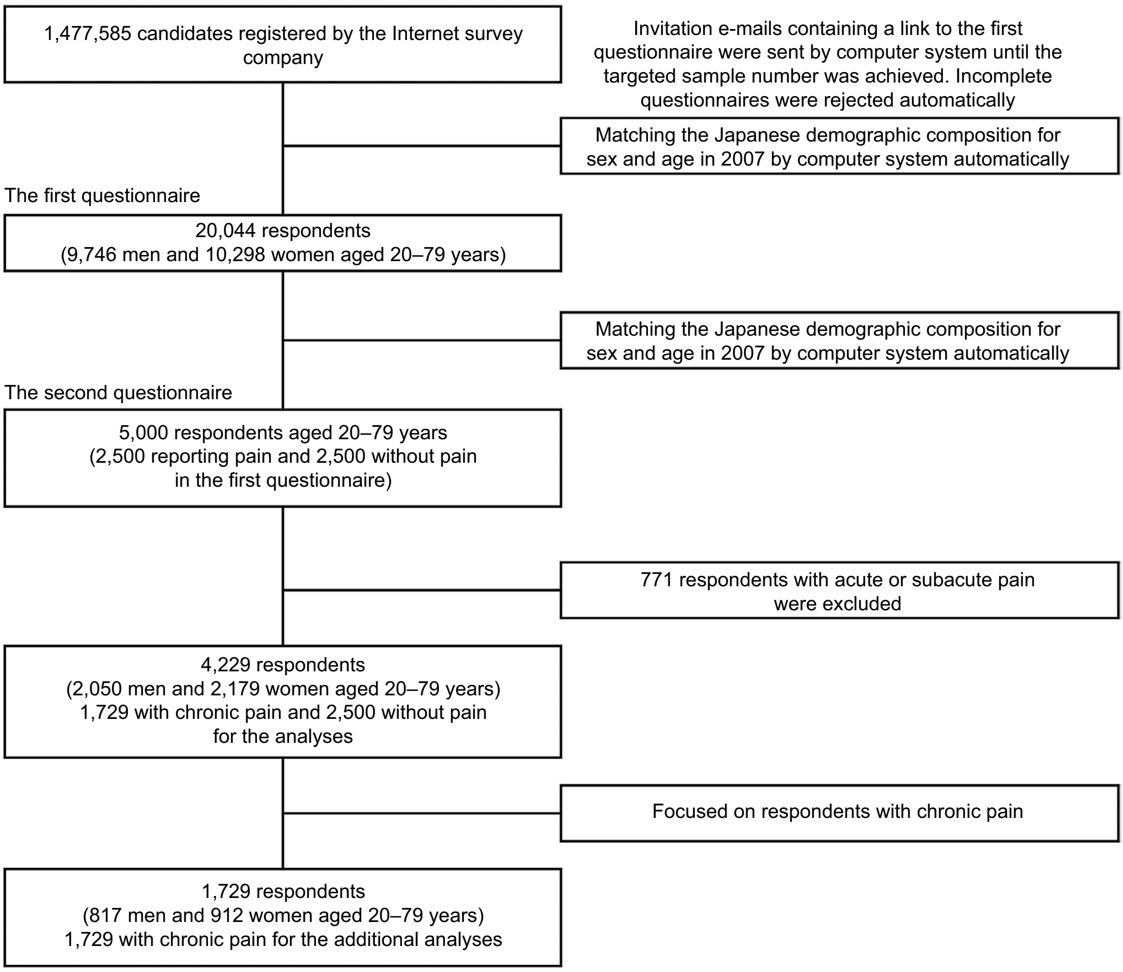

Figure 1 Flowchart of the sampling procedure ending in the sample being analyzed in the current study.

ranging from 0 (not at all) to 4 (extremely), regarding each of seven symptoms during the past 7 days: faintness or dizziness, pain in the heart or chest, nausea or upset stomach, trouble catching one's breath, numbness or tingling in parts of one's body, feeling weak in parts of one's body, and hot or cold spells.[20] Endorsing a response of 2, 3, or 4 was considered presence of the symptom. The number of symptoms with this level of response was counted; the totals ranged from zero to seven symptoms. We defined respondents with ≥3 symptoms, the highest tertile of the symptom count in our data, as existence of the somatizing tendency.

Mental status

We used the Mental Health Inventory (MHI-5), which is identical to the 36-item Short Form Health Survey (SF-36) "Mental Health" domain, to measure mental status.[21,22] The MHI-5 includes the following five questions: "How much of the time during the last month have you: 1) been a very nervous person?, 2) felt downhearted and blue?, 3) felt calm and peaceful?, 4) felt so down in the dumps that nothing could cheer you up?, and 5) been a happy person?". The respondents choose a number from 1 (all of the time) to 6 (none of the time).[21] The total score, which ranges from 5 to 30 points, is converted to a 100-point scale.[21] A previous Japanese study validated the cut point of <52 on the MHI-5 as screening for severe depressive symptoms.[21]

Statistical analysis

A Student's *t*-test was conducted to test for differences in age-adjusted mean values and proportions of risk factors for chronic pain. A chi-square test was performed to test for sex differences in the proportion of ELA.

Three outcomes were measured in the current study, 1) chronic pain prevalence among all respondents, 2) chronic multisite pain (≥3 sites) prevalence, and 3) multiple somatic symptoms (≥3 symptoms) among respondents with chronic pain, as these variables related to the presence or absence of ELA.

Multivariable-adjusted odds ratios (ORs) with 95% confidence intervals (CIs) were calculated using a logistic regression model to compare respondents with and without ELA.

p-Values <0.05 for two-tailed tests were considered statistically significant. All statistical analyses were performed using SAS version 9.4 (SAS Institute, Inc., Cary, NC, USA).

Confounding variables

We adjusted all analyses for the following confounding variables: age, smoking status (never, ex-smoker, or current smoker), have an exercise routine (exercise longer than 30 minutes more than twice a week; yes or no), sleep time (hours/day), body mass index (kg/m^2, categorized in quintiles), household expenditure (JPY/month), and the full distribution of scores on the MHI-5.

We further adjusted for pain intensity (the NRS that ranged from 0 to 10, i.e., 0=no pain, 10=worst pain imaginable) when we analyzed the data for respondents with chronic pain.

Results

Table 1 shows age-adjusted mean values of chronic pain risk factors according to the existence of ELA. Men with ELA were older (52.0 vs. 47.9 years), were more likely to have an exercise routine (45.9% vs. 33.7%), had a higher prevalence of body mass index ≥25 (31.8% vs. 24.8%), had higher household expenditures (380,000 vs. 293,000 JPY/month), had a higher proportion of severe depressive symptoms (27.3% vs. 19.5%), and had a higher prevalence of chronic pain (53.7% vs. 38.0%) compared with those who did not report ELA. Women with ELA had a higher prevalence of body mass index ≥25 (20.7% vs. 11.9%), severe depressive symptoms (38.5% vs. 20.2%), chronic pain (55.0% vs. 39.7%), and severe intensity of pain (6.5% vs. 6.1%) compared with those without it.

The prevalence of ELA was higher in women than in men (14.2% of women, 11.8% of men; $p<0.01$).

Multivariable-adjusted ORs of chronic pain prevalence of respondents with ELA are shown in Table 2. Multivariable-adjusted OR of chronic pain prevalence of men with ELA was 1.62 (1.22–2.15, $p<0.01$), and that of women with ELA was 1.47 (1.13–1.90, $p<0.01$).

Table 3 indicates multivariable-adjusted ORs of multisite pain (≥3 sites) among chronic pain sufferers with ELA. ELA was associated with higher risk for multisite pain among female chronic pain patients: multivariable-adjusted OR was 1.78 (1.22–2.60, $p<0.05$). However, there was no such association for men: multivariable-adjusted OR was 1.38 (0.88–2.16, $p=0.26$).

Table 1 Age-adjusted mean values and proportions of chronic pain risk factors

Chronic pain risk factors	Early-life adversity (–)	Early-life adversity (+)
Men		
n=2,050	1,808	242
Age, years, mean (SE)	47.9 (0.4)	52.0 (1.0)*
Current smoker, %	27.8	28.1
Have an exercise habit, %	33.7	45.9**
Sleep time <5 hours, %	3.4	5.0
Body mass index ≥25, %	24.8	31.8***
Household expenditure (*10,000 JPY/month)	29.3	38.0***
Severe depressive symptoms, %	19.5	27.3*
Chronic pain, % (no. of respondents with chronic pain=817)	38.0	53.7*
Intensity of pain among respondents with chronic pain (0–10 scale)	5.7	5.7
Women		
n=2,179	1,870	309
Age, years, mean (SE)	48.8 (0.4)	49.0 (0.9)
Current smoker, %	14.9	18.4
Have an exercise habit, %	29.0	33.3
Sleep time <5 hours, %	2.5	3.6
Body mass index ≥25, %	11.9	20.7*
Household expenditure (*10,000 JPY/month)	27.1	25.5
Severe depressive symptoms, %	20.2	38.5*
Chronic pain, % (no. of respondents with chronic pain=912)	39.7	55.0*
Intensity of pain among respondents with chronic pain (0–10 scale)	6.1	6.5***

Notes: Test for significance difference from the category of no early-life adversity: *$p<0.001$, **$p<0.01$, ***$p<0.05$.
Abbreviation: SE, standard error.

Table 2 ORs and 95% CIs of chronic pain prevalence of respondents with early-life adversity

	Early-life adversity (–)	Early-life adversity (+)
Men		
Number of respondents at risk	2,172	294
Number of respondents with chronic pain	687	130
Age-adjusted OR (95% CI)	1.00	1.86 (1.42–2.43)*
Multivariable-adjusted OR (95% CI)	1.00	1.62 (1.22–2.15)**
Women		
Number of respondents at risk	2,178	356
Number of respondents with chronic pain	742	170
Age-adjusted OR (95% CI)	1.00	1.86 (1.46–2.37)*
Multivariable-adjusted OR (95% CI)	1.00	1.47 (1.13–1.90)**

Notes: ORs are adjusted for age, smoking status, exercise routine, sleep time, body mass index, personal consumption expenditure, and the full distribution of scores on the Mental Health Inventory-5. Test for significant difference from the category of no early-life adversity: *$p<0.001$, **$p<0.01$.
Abbreviations: CI, confidence interval; OR, odds ratio.

Table 3 ORs and 95% CIs for multisite pain in chronic pain sufferers with early-life adversity

	Early-life adversity (–)	Early-life adversity (+)
Men		
Number of chronic pain sufferers	687	130
Number of chronic pain sufferers with multisite pain (≥3)	283	59
Age-adjusted OR (95% CI)	1.00	1.57 (1.06–2.34)***
Multivariable-adjusted OR (95% CI)	1.00	1.38 (0.88–2.16)
Women		
Number of chronic pain sufferers	742	170
Number of chronic pain sufferers with multisite pain (≥3)	379	117
Age-adjusted OR (95% CI)	1.00	2.27 (1.62–3.18)*
Multivariable-adjusted OR (95% CI)	1.00	1.78 (1.22–2.60)**

Notes: Adjusted for age, smoking status, exercise routine, sleep time, body mass index, household expenditure, the full distribution of scores on the Mental Health Inventory-5, and intensity of pain.Test for significant difference from the category of no early-life adversity: *$p<0.001$, **$p<0.01$, ***$p<0.05$.
Abbreviations: CI, confidence interval; OR, odds ratio.

Table 4 ORs and 95%CIs for multiple somatic symptoms among chronic pain sufferers with early-life adversity versus no early-life adversity

	Early-life adversity (–)	Early-life adversity (+)
Men		
Number of chronic pain sufferers	687	130
Number of multiple somatic symptoms (≥3)	283	59
Age-adjusted OR (95% CI)	1.00	1.57 (1.06–2.34)***
Multivariable-adjusted OR (95% CI)	1.00	1.27 (0.83–1.94)
Women		
Number of chronic pain sufferers	742	170
Number of multiple somatic symptoms (≥3)	379	117
Age-adjusted OR (95% CI)	1.00	2.10 (1.46–3.00)*
Multivariable-adjusted OR (95% CI)	1.00	1.89 (1.27–2.83)**

Notes: Adjusted for age, smoking status, exercise routine, sleep time, body mass index, household expenditure, the full distribution of scores on the Mental Health Inventory-5, and intensity of pain. Test for significant difference from the category of no early-life adversity: *$p<0.001$, **$p<0.01$, ***$p<0.05$.
Abbreviations: CI, confidence interval; OR, odds ratio.

In Table 4, ORs of multiple somatic symptoms (≥3 symptoms) for ELA among chronic pain sufferers are shown. The multivariable-adjusted OR of multiple somatic symptoms was 1.89 (1.27–2.83, $p<0.01$) for women with ELA. For men, ELA was not associated with somatic symptoms.

Discussion

The aim of this study was to examine the sex-specific impact of ELA on chronic pain, chronic multisite pain, and somatizing tendency with chronic pain. We hypothesized that ELA would have long-term adverse impact, which manifested as chronic pain on more women than men. The association of ELA with chronic multisite pain and with somatizing tendency among chronic pain sufferers supported our hypothesis. Although the significant associations were observed in women only, there was no sex difference in the association of ELA with the prevalence of chronic pain. Data from the Adverse Childhood Experience (ACE) study, which included 17,337 adults in the USA, also showed that ELA was associated with the prevalence of headache and with more frequent headaches in women than in men.[23]

ELA may reduce the volume of the hippocampus and prefrontal cortex; this reduction has been linked to major depression and to trait anxiety in adulthood, and predicts sensitivity to future stress events.[24,25] A magnetic resonance imaging study showed that 38 patients with chronic back pain and 30 patients with complex regional pain syndrome had a significantly smaller volume of bilateral hippocampal tissue than those of 50 healthy volunteers, whereas 20 patients with osteoarthritis did not.[26] Additionally, mice with neuropathic pain, in comparison with sham mice, showed more cellular and molecular changes linked to reduction of hippocampal function,[26] so reduction in the volume of the hippocampus due to ELA may actually cause chronic pain.

Moreover, sex differences in central sensitization could support our results. Central sensitization is the phenomenon in which nociceptive pain input from the peripheral nervous system triggers a prolonged but reversible synaptic change of pain pathways in the central nervous system.[27] Central sensitization contributes to the development of persistent pain hypersensitivity, spreads pain sensitivity across peripheral nerve territories without inflammation,[27] and amplifies pain from rheumatoid arthritis, osteoarthritis, fibromyalgia, and headache, as well as neuropathic pain, complex regional pain syndrome, and postsurgical pain.[27] Sex differences in enhanced pain sensitivity among patients with symptomatic knee osteoarthritis have been reported.[28]

In a psychological approach to chronic pain patients, especially women complaining of multisite pain or exhibiting somatizing tendencies, an intervention that addresses ELA should be considered.

Limitations

There were some limitations in this study. First, recall bias could exist because the current study was a cross-sectional design. The fact that people with persistent chronic pain are more likely to recall their ELA has been documented elsewhere.[29] Second, we used a simple and unvalidated question on ELA. A previous study of ELA among adolescents used a semi-structured interview that had good inter-rater reliability, and that study reported an association between ELA and depression.[30] Like that study, the current investigation concluded that respondents with ELA showed a higher prevalence of depressive syndrome than did those without it. We believe that our single item on ELA was an appropriate proxy for the validated questionnaire. Third, the respondents may not be truly representative of the general population in Japan. The sampling issues with web-based surveys have been described previously.[31] Elderly people often have difficulty participating in such surveys. Moreover, the decision to respond to the survey may constitute selection bias, that is, the respondents who were suffering from chronic pain may have been particularly interested in pain research.

Conclusion

ELA was associated with a higher prevalence of chronic pain in both sexes, and with chronic multisite pain and somatizing tendency among women with chronic pain in the Japanese general population.

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Disclosure

The authors report no conflict of interest in this work.

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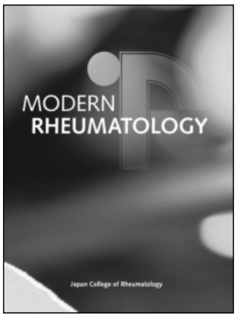

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Relationship between roentgenographic joint destruction in the hands and functional disorders among patients with rheumatoid arthritis

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ORIGINAL ARTICLE

Relationship between roentgenographic joint destruction in the hands and functional disorders among patients with rheumatoid arthritis

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Abstract

Objectives: Although a relationship between joint destruction and functional disorders seems apparent in patients with rheumatoid arthritis (RA), it has not been well proven in the literature. The aims of this study were to clarify the relationship between roentgenographic joint destruction in the hands and functional disorders in patients with RA, and to explore the appropriate assessment measures for functional disorders.
Methods: Cross-sectional data of the Genant-modified Total Sharp Score (Genant-mTSS), Health Assessment Questionnaire-Disability Index (HAQ-DI), Disabilities of the Arm, Shoulder, and Hand (DASH), and Michigan Hand Outcomes Questionnaire (MHQ) were collected from 50 consecutive RA patients and analyzed.
Results: HAQ-DI, DASH, and MHQ had close correlations with Genant-mTSS, with correlation coefficients of 0.69, 0.71, and −0.70, respectively, among patients with low disease activity (DAS28 < 3.2). A floor effect was observed in HAQ-DI, but neither floor nor ceiling effects were observed in DASH and MHQ. Both DASH and MHQ were strongly correlated with HAQ-DI, with correlation coefficients of 0.87 and 0.73, respectively.
Conclusions: Functional disorders had significant relationships with roentgenographic joint destruction in the hands among RA patients with low disease activity. As assessment measures of functional disorders, DASH and MHQ had no floor or ceiling effects, being different from HAQ-DI.

Keywords

Disabilities of the Arm, Shoulder, and Hand, Health Assessment Questionnaire, Michigan Hand Outcomes Questionnaire, Patient reported outcomes, Total Sharp Score

History

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Introduction

Rheumatoid arthritis (RA) is characterized by polyarticular synovial inflammation, and chronic synovitis causes destruction of cartilage and bone [1]. The ''treat-to-target'' strategy using disease-modifying anti-rheumatic drugs (DMARDs) and/or biologics is widely accepted, and one of the important treatment goals is to prevent or reduce functional disorders caused by joint destruction [2].

Recently, strong bisphosphonates and anti-receptor activator of NF-kappa B ligand drugs have been proven to be very effective for osteoporosis and metastatic bone diseases [3,4], implying the possibility that these drugs may directly prevent or repair joint destruction in patients with RA and subsequently reduce functional disorders.

Before testing this therapeutic approach for functional disorders in RA patients, whether their joint destruction is actually related to functional disorders should be clarified. In addition, the choice of appropriate assessment measures for functional disorders needs to be discussed.

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The Total Sharp Score (TSS), which is calculated from X-ray films of the hands and feet, is widely used to quantify the joint destruction in RA patients [5–7]. For evaluation of functional disorders, the Health Assessment Questionnaire (HAQ) is commonly used for RA patients [8]. However, other measures, such as the Disabilities of the Arm, Shoulder, and Hand (DASH) [9,10] designed for assessment of the upper extremities and the Michigan Hand Outcomes Questionnaire (MHQ) [11,12] for specialized assessment of the hands, could be more appropriate than the HAQ when the hands are focused upon for assessment.

In the present study, we aimed to assess the relationship between roentgenographic joint destruction in the hands and functional disorders using several assessment measures. In addition, we assessed which measures are appropriate for the evaluation of functional disorders.

Methods

The study protocol was reviewed and approved by the research ethics committees of The University of Tokyo Hospital. Cross-sectional data were collected from 50 consecutive patients with RA at the clinic in The University of Tokyo Hospital in 2013 after receiving written informed consent. The subjects consisted of 46 women and four men, with a mean age of 62 years.

To quantify the joint destruction, X-ray examinations of both hands were performed and the Genant-modified TSS

Table 1. Demographic data of the patients.

Sex (female:male)	46:4
Age (years)	62 ± 11*
BMI (kg/m^2)	22 ± 3.5*
Disease duration (years)	16 ± 12*
No. of patients using DMARDs	46 (92%)
No. of patients using biologics	15 (30%)
No. of patients using steroids	22 (44%)
DAS28-ESR	3.2 ± 1.1*
Genant-mTSS	43 ± 37*
HAQ-DI	0.34 ± 0.47*
DASH	21 ± 19*
MHQ†	59 ± 16*
Grip strength (mmHg)	200 ± 79*
Pinch strength (kg)	4.0 ± 2.2*

*Data represent the mean ± SD.
†Mean of total scores of both hands.

(Genant-mTSS) was calculated. To evaluate the functional disorders, data for the validated Japanese translations of HAQ-Disability Index (HAQ-DI) [13], DASH [10], and MHQ [12] were collected. For the MHQ, the mean total scores of the MHQ in both hands were used for analysis. Japanese translation of MHQ had not been validated at the time of data collection, but we obtained and used the same version as the one which was later validated and published by Oda et al. [12].

Grip strength was measured with a mercury hand dynamometer (Acoma, Tokyo, Japan) and the mean strength of the right and left hands was used for analysis. Pinch strength was measured with a JAMAR hydraulic pinch gauge (Sammons Preston Rolyan, Bolingbrook, IL) and the mean strength of the right and left hands was used for analysis.

To test the relationship between functional disorder and joint destruction of the hand, correlations between Genant-mTSS and HAQ-DI, DASH, MHQ, grip strength, and pinch strength were analyzed. To test the usefulness of DASH and MHQ as assessment measures for functional disability, analyses were performed using HAQ-DI as the reference value.

For statistical assessments, we used SPSS Statistics version 21 (IBM Japan, Tokyo, Japan). Pearson's product–moment correlation analysis was employed to evaluate the relationship between two components, and a receiver-operating characteristic (ROC) analysis was used to determine cut-off scores. Values of $p < 0.01$ were considered to indicate statistical significance.

A ceiling or floor effect was defined to exist when the mean ± SD outranged the score range. Specifically, when the mean plus SD exceeded the highest score of the measure, it was referred to as a ceiling effect, and when the mean minus SD was below the lowest score of the measure, it was referred as a floor effect.

Results

The demographic data are shown in Table 1. The mean disease duration of RA was 16 years, and the proportions of patients using DMARDs, biologics, and steroids were 92%, 30%, and 44%, respectively. The mean values for the Disease Activity Score 28 (DAS28), Genant-mTSS, HAQ-DI, DASH, and MHQ were 3.2, 43, 0.34, 21, and 59, respectively. The mean grip strength and pinch strength were 200 mmHg and 4.0 kg, respectively.

Plots of the Genant-mTSS and individual functional scores are shown in Figure 1. HAQ-DI, DASH, and MHQ had moderate correlations with Genant-mTSS, with correlation coefficients of 0.51, 0.53, and −0.61, respectively. The correlation coefficient for MHQ had a negative value, because higher scores of MHQ indicated lower functional disability. Neither grip strength nor pinch strength had significant correlations with Genant-mTSS. No significant relationship was observed between DAS28 and HAQ-DI, DASH, or MHQ.

The subjects were divided into 20 patients with high disease activity (DAS28 ≥ 3.2) and 30 patients with low disease activity (DAS28 < 3.2) (Figure 1B,C). Among the patients with high disease activity, there were no significant correlations between Genant-mTSS and functional scores (Figure 1B). Meanwhile, close correlations between Genant-mTSS and all functional scores were found among patients with low disease activity (Figure 1C). A floor effect, or bottoming out of the score on zero, was observed in HAQ-DI. Neither floor nor ceiling effects were observed in DASH and MHQ.

As HAQ-DI is the established assessment measure for evaluating the functional disability of patients with RA, we assessed DASH and MHQ using HAQ-DI as the reference value. Plots of HAQ-DI (horizontal axis) and DASH and MHQ (vertical axis) are shown in Figure 2. Both DASH and MHQ were strongly correlated with HAQ-DI, with correlation coefficients of 0.87 and 0.73, respectively.

The cut-off score equivalent to HAQ-DI =0.5, which is widely accepted as the threshold for functional remission, was 26 and 55 in DASH and MHQ, respectively according to ROC analyses (Figure 3). The sensitivity and specificity were 86% and 100% for DASH, and 78% and 100% for MHQ, respectively. The area under the curve was 0.96 and 0.91 for DASH and MHQ, respectively.

Discussion

In patients with RA, functional disorders are dependent on disease activity and joint destruction [14]. Although a relationship between joint destruction and functional disorders seems apparent, it has not been well proven in the literature [15].

The present study revealed significant correlations between Genant-mTSS as a measure for joint destruction and functional measures such as HAQ-DI, DASH, and MHQ. The correlations were high among patients with low disease activity and low among patients with high disease activity, which supposedly reflects that functional disorders are affected by both disease activity and structural destruction.

HAQ-DI is a patient-reported measure of systemic functional disorders [8]. It is widely used as a measure to evaluate functional disorders in patients with RA, and HAQ-DI ≤0.5 is an accepted cut-off value for functional remission [16]. However, ceiling and floor effects have been pointed out [17].

DASH is a patient-reported assessment measure of the upper extremities created by the American Academy of Orthopaedic Surgeons [9]. MHQ is a patient-reported assessment measure established at Michigan University and is specialized for the hands [11]. These two measures have not been frequently applied for patients with RA, and their efficacies for evaluating functional disorders in RA patients have not been well discussed [18]. In the present study, we found that both DASH and MHQ had significant relationships with roentgenographic joint destruction in the hands, especially among patients with low disease activity. In addition, DASH and MHQ did not have floor or ceiling effects, being different from HAQ-DI. The results of our study indicate that DASH and MHQ are valuable assessment measures, and is superior to HAQ-DI, for evaluating functional disorders of the hands in patients with RA.

This study has some limitations. First, the patients included in our study were longstanding RA cases, whose mean duration of the disease was 16 years. We need further investigation to clarify if our findings in the study are independent of disease duration. Second, the explanation of the obtained results about patients with high disease activity is unclear. Although we guess functional disorder is explained in most part by disease activity and joint

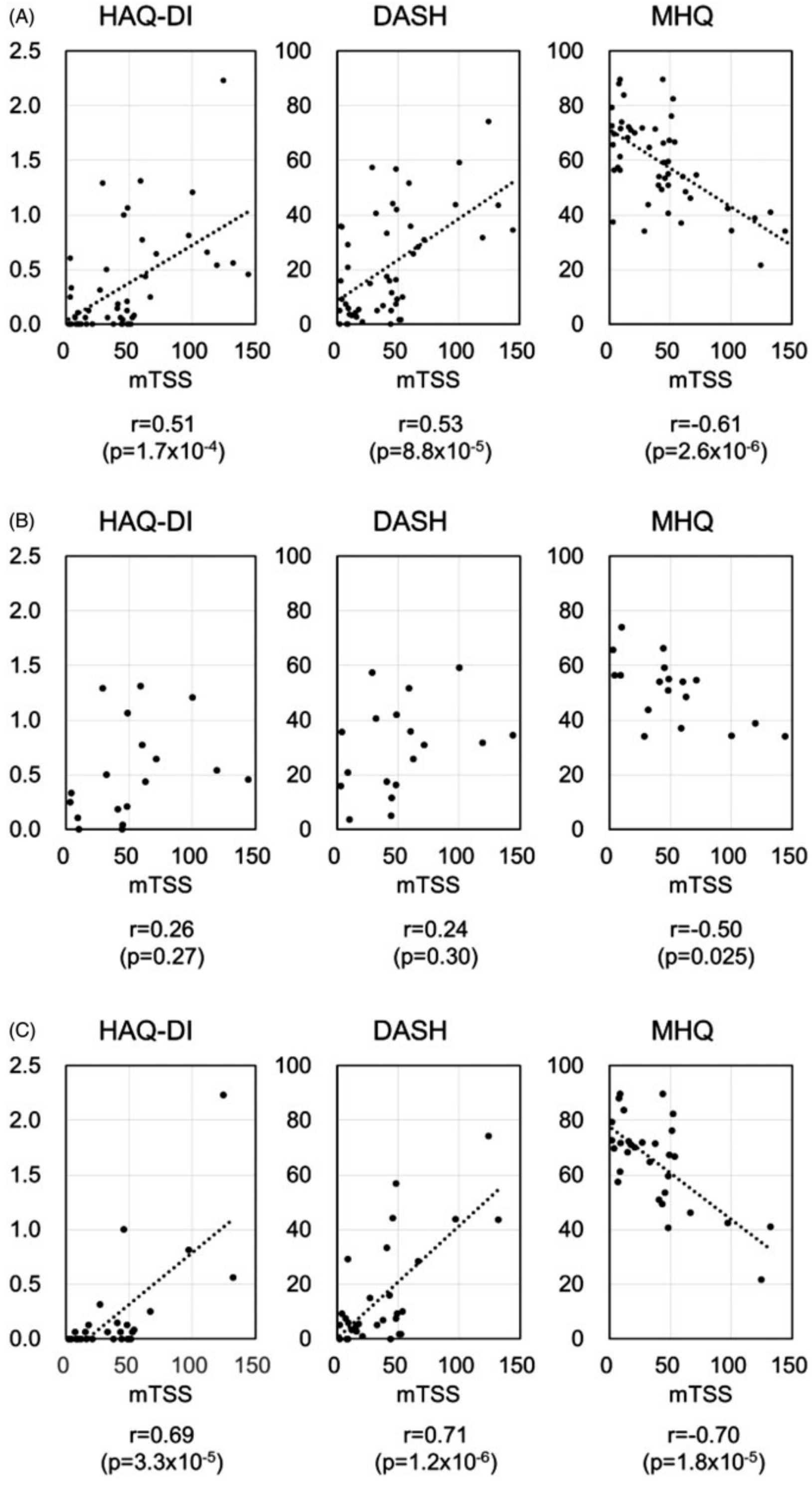

Figure 1. (A) Plots of Genant-mTSS and functional scores (HAQ-DI, DASH, and MHQ) for all patients. The dotted lines show the regression lines. The correlation coefficient of MHQ has a negative value, because high MHQ scores mean low functional disability. (B) Plots of Genant-mTSS and functional scores (HAQ-DI, DASH, and MHQ) for patients with high disease activity (DAS28 $\geq$ 3.2). It should be noted that no correlations are observed. (C) Plots of Genant-mTSS and functional scores (HAQ-DI, DASH, and MHQ) for patients with low disease activity (DAS28 $<$ 3.2). It should be noted that HAQ-DI, DASH, and MHQ are closely correlated with Genant-mTSS, and that a floor effect is observed for HAQ-DI while no floor and ceiling effects are observed for DASH and MHQ. The correlation coefficients are shown by the *r*-values.

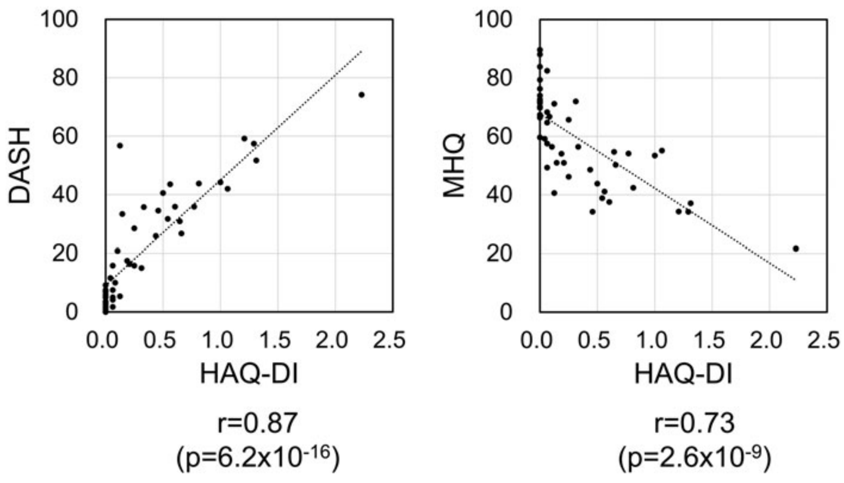

Figure 2. Plots of HAQ-DI with DASH and MHQ. It should be noted that both DASH and MHQ are strongly correlated with HAQ-DI.

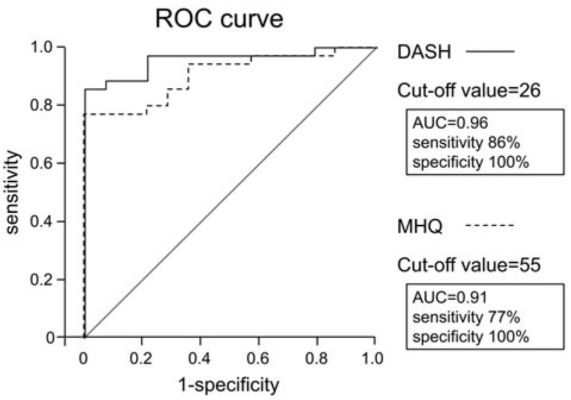

Figure 3. ROC curves for DASH and MHQ predicting HAQ-DI $\geq$0.5. The cut-off score equivalent for HAQ-DI =0.5 was 26 and 55 in DASH and MHQ, respectively. Note that AUC are as high as 0.96 and 0.91 in DASH and MHQ, respectively, indicating the high predictive accuracy.

destruction, the number of cases in our study is not enough for assessment.

Conclusions

Roentgenographic joint destruction in the hands had significant relationships with functional disorders among RA patients with low disease activity. DASH and MHQ are valuable assessment measures for evaluating functional disorders of the hands in patients with RA.

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Conflict of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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ORIGINAL ARTICLE

Is osteoporosis a predictor for future sarcopenia or vice versa? Four-year observations between the second and third ROAD study surveys

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Abstract
Summary In a 4-year follow-up study that enrolled 1099 subjects aged ≥60 years, sarcopenia prevalence was estimated at 8.2%. Moreover, the presence of osteoporosis was significantly associated with short-term sarcopenia occurrence, but the reciprocal relationship was not observed, suggesting that osteoporosis would increase the risk of osteoporotic fracture and sarcopenia occurrence.
Introduction The present 4-year follow-up study was performed to clarify the prevalence, incidence, and relationships between sarcopenia (SP) and osteoporosis (OP) in older Japanese men and women.
Methods We enrolled 1099 participants (aged, ≥60 years; 377 men) from the second survey of the Research on Osteoarthritis/Osteoporosis against Disability (ROAD) study (2008–2010) and followed them up for 4 years. Handgrip strength, gait speed, skeletal muscle mass, and bone mineral density were assessed. SP was defined according to the Asian Working Group for Sarcopenia. OP was defined based on the World Health Organization criteria.
Results SP prevalence was 8.2% (men, 8.5%; women, 8.0%) in the second survey. In those with SP, 57.8% (21.9%; 77.6%) had OP at the lumbar spine L2–4 and/or femoral neck. SP cumulative incidence was 2.0%/year (2.2%/year; 1.9%/year). Multivariate regression analysis revealed that OP was significantly associated with SP occurrence within 4 years (odds ratio, 2.99; 95% confidence interval, 1.46–6.12; $p < 0.01$), but the reciprocal relationship was not significantly observed (2.11; 0.59–7.59; $p = 0.25$).
Conclusions OP might raise the short-term risk of SP incidence. Therefore, OP would not only increase the risk for osteoporotic fracture but may also increase the risk for SP occurrence.

Keywords Incidence · Osteoporosis · Osteosarcopenia · Population-based cohort study · Sarcopenia

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Introduction

As the average age of the human population increases, there is an urgent need to develop strategies to prevent musculoskeletal disorders, which can impair activities of daily life (ADL) and quality of life (QOL) in the elderly. Sarcopenia (SP) and osteoporosis (OP) are major musculoskeletal diseases that impair ADL and QOL, leading to increased morbidity and mortality rates in the elderly. The recent National Livelihood Survey performed by the Ministry of Health, Labour, and Welfare in Japan [1] found that falls and osteoporotic fractures are ranked fourth, and frailty, to which muscle weakness and low physical performance contribute largely, was ranked third among the causes of disabilities requiring support and long-term care. Therefore, developing approaches to prevent SP and OP could reduce ADL and QOL impairments and subsequent disabilities among the elderly.

In the elderly, SP is characterized by generalized loss of skeletal muscle mass and muscle strength and/or function, causing multiple adverse health outcomes, including physical disability, poor QOL, and death [2–7]. Although cross-sectional studies have investigated SP prevalence [8–14], the epidemiologic evidence of population-based samples remained insufficient. This might be because a widely accepted definition of SP was not established until the European Working Group on Sarcopenia in Older People (EWGSOP) developed a practical clinical definition and diagnostic criteria in 2010 [5]. There is a growing consensus that SP should not be defined based on muscle mass alone but also on muscle strength and function [5]. After publication of the EWGSOP consensus criteria, the Asian Working Group for Sarcopenia (AWGS) announced the appropriate diagnostic cutoff values for Asian populations [15]. In the AWGS consensus report, the reasons for creating different cutoff values from the European criteria were stated as follows: although the recommended approaches for measurements of muscle mass, muscle strength, and physical performance by AWGS were similar to the EWGSOP definition, the cutoff values of these measurements in Asian populations may differ from those in Caucasians because of ethnicities, body size, lifestyles, and cultural backgrounds. Therefore, developing an Asian consensus for sarcopenia diagnosis based on the evidence derived from Asian populations is essential for research and therapeutic approaches to sarcopenia in Asia [15]. This definition is now used widely for the assessment of SP in Asian countries.

The Research on Osteoarthritis/Osteoporosis Against Disability (ROAD) study is a prospective cohort study aimed at elucidating the environmental and genetic background of musculoskeletal diseases [16, 17]. The baseline data and that from the second survey of the ROAD study provided information on the prevalence and incidence of OP at the lumbar spine L2–4 and proximal femur [17, 18]. Furthermore, the prevalence of SP was evaluated using the EWGSOP definition in the second ROAD survey, giving an estimated prevalence in the general Japanese population of 13.8% in men and 12.4% in women [19]. The same study revealed that SP prevalence increased in an age-dependent manner in both sexes [19]. However, the SP incidence according to the AWGS criteria has not been investigated. Furthermore, the relationships of SP with other musculoskeletal diseases, especially OP, have not been determined, and it is not clear whether SP causes OP development, OP causes SP development, the conditions are comorbid, or if SP and OP represent concomitant modifications of one another.

In the present study, we completed the third ROAD study survey, a 4-year follow-up in which examinations identical to those in the second ROAD study survey were conducted. The aims of the present study were to clarify SP prevalence and incidence using the AWGS criteria, determine the co-existing proportions of SP and OP, and evaluate whether there was a significant contribution of SP to subsequent OP development, or vice versa, in elderly Japanese subjects.

Methods

Study participants

The present study was performed using the ROAD study cohorts that were established in 2005. The ROAD study is a national, prospective study of osteoarthritis that consists of population-based cohorts from several communities in Japan. Details of the cohort profiles have been reported elsewhere [16, 17]. In brief, between 2005 and 2007, a baseline database was created that included clinical and genetic information for 3040 residents (1061 men and 1979 women with a mean age of 70.3 (standard deviation [SD], 11.0) years; 71.0 (10.7) years in men, 69.9 (11.2) years in women). The subjects were recruited from resident registration listings in 3 communities with different characteristics: 1350 subjects from an urban region in Itabashi, Tokyo; 864 subjects from a mountainous region in Hidakagawa, Wakayama; and 826 subjects from a coastal region in Taiji, Wakayama.

After the baseline study, a second survey was performed in the same communities from 2008 to 2010 [20], and the third survey was followed from 2012 to 2013. In the second and third surveys, in addition to the OP assessment, examinations for the diagnosis of SP, including measurements such as gait speed, grip strength, and skeletal muscle mass were initiated in mountainous and coastal regions. In the present study, among the 1551 participants (521 men and 1030 women) in the second survey from mountainous and coastal regions who underwent all measurements for SP and OP, those aged ≥60 years were selected based on the AWGS criteria for SP [15]. As a result, 1099 (377 men and 722 women; mean age, 72.1 (7.4) years [72.7 (7.5) years in men, 71.8 (7.4) years in women]) participants were recruited as eligible subjects. A flow chart of subjects' recruitment and follow-up with reasons for dropout is shown in Fig. 1. The data obtained from these 1099 subjects was used to clarify mutual associations between SP and OP.

Examinations performed during the second ROAD study survey

Interviewer-administered questionnaire

Participants completed an interviewer-administered questionnaire that consisted of 200 questions related to lifestyle

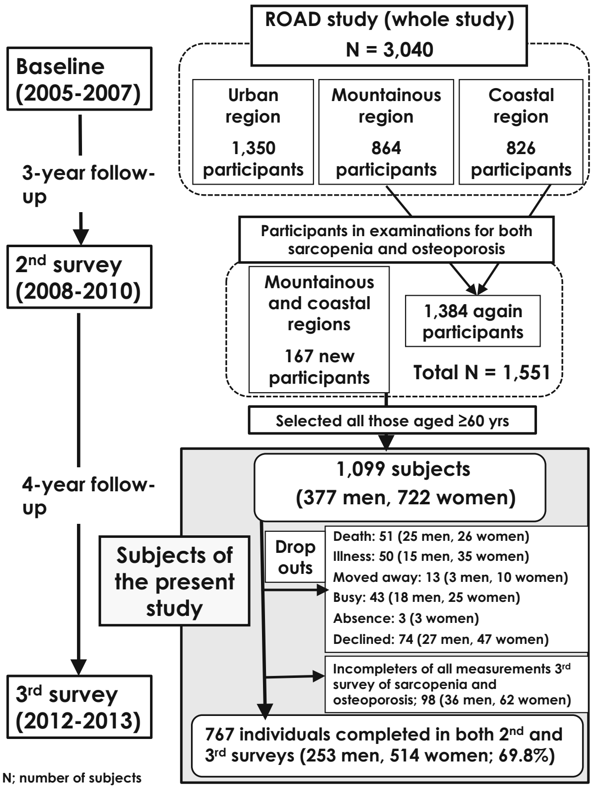

Fig. 1 Flow chart of the recruited participants in the present study

including occupation, smoking habits, alcohol consumption, family history, medical history, physical activity, reproductive history, and health-related QOL.

Anthropometric measurements and medical history

Anthropometric measurements, including height and weight, were measured in all participants. Body mass index (BMI; weight [kg]/height [m^2]) was calculated as weight in kilograms divided by height in meters squared. Experienced orthopedic surgeons collected medical information about pain, swelling, and the range of motion of the knee.

Skeletal muscle mass

Skeletal muscle mass was measured by bioimpedance analysis [21–25] using the Body Composition Analyzer MC-190 (Tanita Corp., Tokyo, Japan). The protocol was described by Tanimoto et al. [11, 13] and has been validated previously [26]. Appendicular skeletal muscle mass (ASM) was calculated as the sum of the muscle mass of the arms and legs. Absolute ASM was converted to an appendicular muscle mass index by dividing by height in meters squared (kg/m^2).

Muscle strength and walking speed

Handgrip strength was measured using a Toei Light handgrip dynamometer (Toei Light Co. Ltd., Saitama, Japan) to assess muscle strength. Both hands were tested and the largest value used to determine the maximum muscle strength. The usual walking speed was measured as an index of physical performance. The time taken (s) to walk 6 m at normal walking speed was recorded, and the usual gait speed was calculated.

BMD examination

Lumbar spine and proximal femur bone mineral density (BMD) values were determined using dual-energy X-ray absorptiometry (DXA; Hologic Discovery C; Hologic, Waltham, MA). To control DXA precision, the equipment was checked at every examination during the second and third surveys using the same phantom. The BMD of the phantom was regulated to within ±1.5% during all examinations. In addition, the same physician (N.Y.) examined all participants to control observer variability. Intraobserver variability of DXA using the Lunar DPX in vitro and in vivo had been measured by the same physician (N.Y.) in another study [27], and the coefficient of variance for L2–4 in vitro was 0.35%. The coefficients of variance for L2–4, the proximal femur, Ward's triangle, and the trochanter as examined in vivo in five male volunteers were 0.61–0.90, 1.02–2.57, 1.97–5.45, and 1.77–4.17%, respectively.

Definition of SP and OP

SP was determined according to the criteria defined by the AWGS [15]. AWGS criteria were as follows: (A) age ≥60 or ≥65 years; (B) low appendicular skeletal muscle mass, 7.0 kg/m^2 for men and 5.7 kg/m^2 for women, according to bioimpedance analysis; (C) low handgrip strength, <26 kg in men and <18 kg in women; and (D) low gait speed, with usual gait speed being ≤0.8 m/s. Subjects were diagnosed as having SP if they had criteria A and B and either of criteria C or D. Regarding age definition using the AWGS criteria, because of the different states of aging in Asia, not all countries use the same cutoff age to define elderly populations. Therefore, the AWGS recommends using either 60 or 65 years as the age for SP. In the present study, we defined subjects aged ≥60 years as potential subjects for SP.

In the present study, OP was defined according to the values of BMD. The World Health Organization criteria were used when BMD T-scores were lower than the peak bone mass by 2.5 SDs [28]. In Japan, the mean L2–4 BMD in young adults, as measured using the Hologic DXA, was 1.011 (0.119) g/cm^2 [29]. Therefore, lumbar spine osteoporosis was defined as an L2–4 BMD of <0.714 g/cm^2. In Japan, the mean femoral neck BMDs in young adult males and females are 0.863 (0.127) and 0.787 (0.109) g/cm^2, respectively [28]. Therefore, OP at the femoral neck was defined as a BMD of <0.546 and <0.515 g/cm^2 for men and women, respectively.

Incidence of SP and OP

The cumulative incidences of SP and OP were determined based on changes in measurements between the second and third surveys. New cases of SP or OP were defined as when an individual did not meet criteria for SP or OP at the second survey but did meet them at the third survey.

Statistical analyses

All statistical analyses were performed using STATA statistical software (STATA Corp., College Station, TX). Differences in proportions were compared using the chi-square test. Differences in continuous variables were tested for significance using analysis of variance for comparisons among multiple groups or Scheffe's least significant difference test for group pairs.

Logistic regression analysis was used to test the association between the presence of SP and OP occurrence. OP occurrence was used as the objective variable, and the presence of SP (1: yes, 0: no) was used as the explanatory variable, after adjusting for age (years), sex (0: men, 1: women), and unconfirmed confounding factors. A second logistic regression analysis was conducted by replacing the objective and explanatory variables in the model mentioned above with SP occurrence and the presence of OP (1: yes, 0: no), respectively. The unconfirmed risk factors used for adjustment in the multivariate logistic analysis included residing area (0: mountainous area, 1: coastal area), emaciated stature (BMI <18.5 kg/m^2; [0: no, 1: yes]), current smoking habit (0: ex or never smoker, 1: current smoker), and alcohol consumption habit (0: ex or never drinker, 1: current drinker).

Results

SP prevalence

SP prevalence according to age group stratifications of 60–64, 65–69, 70–74, 75–79, and ≥80 years were 0.5, 0.0, 4.3, 11.2, and 27.0%, respectively (men, 1.5, 0.0, 4.7, 11.5, and 23.9%, for 60–64, 65–69, 70–74, 75–79, and ≥80 years, respectively; women, 0.0, 0.0, 4.1, 10.9, and 28.7%, for 60–64, 65–69, 70–74, 75–79, and ≥80 years, respectively). Above the age of 70 years, SP prevalence increased in an age-dependent manner, but there was no significant difference in prevalence according to sex.

OP prevalence

OP prevalence estimates were conducted on 1097 participants (376 men, 721 women) because the BMD at the spine L2–4 or femoral neck could not be measured in 2 individuals (1 man, 1 woman). OP prevalence according to age group stratifications of 60–64, 65–69, 70–74, 75–79, and ≥80 years were 10.8, 18.0, 19.5, 34.0, and 44.0%, respectively (men, 1.5, 1.5, 4.7, 13.8, and 11.3%, for 60–64, 65–69, 70–74, 75–79, and ≥80 years, respectively; women, 15.4, 24.8, 26.9, 47.7, and 62.0%, for 60–64, 65–69, 70–74, 75–79, and ≥80 years, respectively). OP prevalence increased in an age-dependent manner in women and was significantly higher in each age strata in women compared with that in men.

SP and OP co-existence

In the population aged ≥60 years, SP and OP co-existence was observed in 4.7%, SP alone was present in 3.5%, OP alone was noted in 20.2%, and 71.7% had neither SP nor OP.

In men, the prevalences of co-existing SP and OP, SP alone, OP alone, and neither SP nor OP were 1.9, 6.7, 5.1, and 86.4%, respectively, and in women, those were 6.2, 1.8, 28.0, and 63.9%, respectively. The difference in distribution in prevalences between men and women was most significant for OP. That is, prevalences of the co-existence of SP and OP and OP alone were significantly higher in women compared with men ($p < 0.001$).

Associated factors classified by the presence or absence of SP or OP

Table 1 shows a comparison of background characteristics for those with and without SP. Among subjects with SP, 57.8% had a concomitant diagnosis of OP, which was a significantly higher proportion than those without SP (22.0%, $p < 0.001$). Similarly, in those with OP, 19.1% had a concomitant diagnosis of SP, which was a significantly greater proportion than those without OP (4.6%, $p < 0.001$).

Diagnostic SP values such as grip strength and usual walking speed were significantly lower in the subjects with OP ($p < 0.001$). In addition, OP diagnostic values such as lumbar spine L2–4 and femoral neck BMD were significantly lower in the subjects with SP ($p < 0.0001$). Age and smaller stature were both significantly associated with SP and OP. Residing region was significantly associated with SP ($p = 0.005$). Being

Table 1 Comparison of characteristics at the second survey classified by the presence or absence of sarcopenia or osteoporosis

	Sarcopenia			Osteoporosis		
	Sarcopenia (−) (n = 1009)	Sarcopenia (+)	p value	Osteoporosis (−) (n = 824)	Osteoporosis (+) (n = 273)	p value
Mean values (SD) and percentage of selected characteristics						
Age (years)	71.3 (7.0)	81.1 (5.9)	<0.0001	71.0 (7.1)	75.5 (7.3)	<0.0001
Female sex (%)	65.8	64.4	0.794	57.5	90.5	<0.001
Height (cm)	154.1 (8.8)	149.0 (8.8)	<0.0001	155.5 (8.7)	148.1 (7.4)	<0.0001
Weight (kg)	55.8 (10.1)	45.6 (8.2)	<0.0001	57.6 (9.8)	47.1 (7.4)	<0.0001
BMI (kg/m^2)	23.4 (3.3)	20.4 (2.4)	<0.0001	23.8 (3.2)	21.5 (3.0)	<0.0001
Emaciation (BMI < 18.5 kg/m^2; %)	5.0	21.1	<0.001	3.3	15.4	<0.001
Residing in a coastal area (%)	47.5	32.2	0.005	46.4	45.8	0.870
Current smoking habit (%)	8.4	10.0	0.613	10.1	4.0	0.002
Current alcohol drinking habit (%)	31.2	25.6	0.268	35.3	16.5	<0.0001
Mean values (SD) of selected measurements for sarcopenia diagnosis						
Grip strength (maximum) (kg)	29.0 (8.6)	20.5 (7.4)	<0.0001	30.2 (8.8)	22.7 (6.0)	<0.0001
Usual walking speed (m/s)	1.10 (0.26)	0.75 (0.19)	<0.0001	1.10 (0.27)	0.99 (0.29)	0.035
Appendicular skeletal muscle mass adjusted by height (kg/m^2)	6.65 (0.99)	5.69 (0.63)	<0.0001	6.80 (0.99)	5.88 (0.69)	<0.001
Prevalence of sarcopenia (%)	0.0	100.0	–	4.6	19.1	<0.001
Measurements related to the presence of osteoporosis						
BMD (L2–4) (g/cm^2)	0.923 (0.207)	0.823 (0.205)	<0.0001	0.981 (0.186)	0.713 (0.129)	<0.0001
BMD (femoral neck) (g/cm^2)	0.640 (0.126)	0.552 (0.119)	<0.0001	0.679 (0.109)	0.492 (0.06)	<0.0001
Prevalence of osteoporosis (L2–4 or femoral neck; %)	22.0	57.8	<0.001	0.0	100.0	–

n number of subjects, *BMI* body mass index, *BMD* bone mineral density, *SD* standard deviation

female and drinking and smoking less were significantly associated with OP (Table 1).

Table 2 (A), (B) shows the mutual associations between the presence of SP and OP at the lumbar spine L2–4 and/or the femoral neck. After adjustment for potential confounding factors mentioned above, logistic regression analysis revealed that the presence of OP was significantly associated with SP presence (odds ratio, 2.86; 95% confidence interval, 1.59–5.13; p < 0.001; Table 2 (A)). Furthermore, the presence of SP was significantly associated with OP presence (odds ratio, 2.78; 95% confidence interval, 1.55–4.99; p < 0.001; Table 2 (B)).

Participants in both the second and third surveys

Among 1099 participants in the second survey who were aged ≥60 years at the assessment of SP, 865 individuals (78.7%, 289 men, 576 women) attended the third survey performed 4 years later. Therefore, 234 individuals (21.3%; 88 men, 146 women) dropped out in the third survey. The reasons for dropout are shown in Fig. 1. Among the 865 participants in both the second and third surveys, 98 (11.3%, 36 men, 62 women) did not have complete measurements for the diagnosis of SP and OP. Therefore, the data from 767 completers (69.8%, 253 men, 514 women) was used in the present study to assess the contribution of OP to the occurrence of SP, and vice versa.

Cumulative incidence of SP

Among 767 completers (253 men, 514 women) of the third survey of the ROAD study, 32 subjects (9 men and 23 women) were diagnosed with SP at the second survey. Therefore, the number of population at risk for SP occurrence was 735 (244 men, 491 women). The cumulative incidence of SP during the 4-year period between the surveys was 2.0%/year (men, 2.2%/year; women, 1.9%/year). Figure 2 shows the age-sex classified SP incidence. The cumulative SP incidences for the at-risk populations according to age group were 0.4, 0.5, 1.5, 4.2, and 6.9%/year for 60–64, 65–69, 70–74, 75–79, and ≥80 years, respectively. The incidence increased in an age-dependent fashion (p < 0.001 for all subjects, p = 0.005 for men, and p < 0.001 for women), but there was no

Table 2 Mutual associations between presence of sarcopenia and osteoporosis among subjects at the second survey

Logistic regression model				
Objective variable	Reference			
A. Effect of the presence of osteoporosis on sarcopenia presence				
Sarcopenia	0: no, 1: yes			
Explanatory variables	Reference	OR	95% CI	*p* value
Osteoporosis at lumbar spine L2–4 or femoral neck	0: no, 1: yes	2.75	1.59–5.13	<0.001
Adjusted factors				
Age (years)	1+ year	1.22	1.17–1.28	<0.001
Sex	0: men, 1: women	0.69	0.37–1.29	0.247
Residing area	0: mountainous area, 1: coastal area	0.63	0.37–1.06	0.082
Emaciation (BMI < 18.5 kg/m^2)	0: no, 1: yes	3.19	1.58–6.44	0.001
Current smoking habit	0: ex or never smoker, 1: current smoker	1.90	0.77–4.67	0.162
Current alcohol drinking habit	0: ex or never drinker, 1: current drinker	0.97	0.53–1.78	0.930
B. Effect of the presence of sarcopenia on osteoporosis presence				
Osteoporosis at lumbar spine L2–4 or femoral neck	0: no, 1: yes			
Explanatory variables	Reference	OR	95% CI	*p* value
Sarcopenia	0: no, 1: yes	2.78	1.55–4.99	0.001
Adjusted factors				
Age (years)	1+ year	1.09	1.06–1.12	<0.001
Sex	0: men, 1: women	8.94	5.43–14.8	<0.001
Region	0: mountainous area, 1: coastal area	1.12	0.82–1.55	0.469
Emaciation (BMI < 18.5 kg/m^2)	0: no, 1: yes	5.28	2.86–9.76	<0.001
Current smoking habit	0: ex or never smoker, 1: current smoker	0.80	0.36–1.75	0.573
Current alcohol drinking habit	0: ex or never drinker, 1: current drinker	0.81	0.53–1.24	0.330

OR odds ratio, *95% CI* 95% confidence interval, *BMI* body mass index

significant difference in incidence according to sex ($p = 0.61$) (Fig. 2).

Cumulative incidence of OP

Among 767 completers (253 men, 514 women), 2 male subjects were excluded from the assessment of OP incidence at the third survey because their BMD measurements for both lumbar spine L2–4 and femoral neck could not be performed. Among the remaining 765 subjects (251 men, 514 women), 90 (2 men and 88 women) were diagnosed with OP at both the lumbar spine L2–4 and femoral neck at the second survey. Therefore, in the present study, the population at risk for OP at the lumbar spine L2–4 and/or femoral neck was 675 subjects (249 men, 426 women). The cumulative OP incidence during the 4-year period between the surveys was 1.9%/year (men, 0.8%/year; women, 2.5%/year). The cumulative OP incidences for the at-risk populations according to age group were 1.1, 2.3, 2.1, 1.7, and 2.7%/year for 60–64, 65–69, 70–74, 75–79, and ≥80 years, respectively (men, 1.0, 1.0, 0.9, 0.0, and 1.5%/year, for 60–64, 65–69, 70–74, 75–79, and ≥80 years, respectively; women, 1.1, 2.9, 2.8, 3.0, and 4.0%/year, for 60–64, 65–69, 70–74, 75–79, and ≥80 years, respectively.) OP incidence was not associated with age ($p = 0.38$ for total subjects, $p = 0.60$ for men, $p = 0.23$ for women), and it was significantly higher in women compared with that in men ($p = 0.001$).

Assessment of contribution of OP to the subsequent occurrence of SP, and vice versa

Table 3 shows the comparison of the background characteristics according to the occurrence or non-occurrence of SP during the 4-year follow-up. Among subjects without SP at the second survey, in addition to higher age, lower height, lower weight, and residing in a mountainous area, the presence of OP was significantly associated with future SP development ($p < 0.001$).

Table 3 also shows the comparison of the background characteristics according to the occurrence or non-occurrence of OP during the 4-year follow-up. In addition to female sex, lower height, lower weight, emaciation, and residing in a mountainous area, the presence of SP was significantly associated with the future incidence of OP ($p = 0.043$).

After adjustment for the potential confounding factors such as, age, sex, regional difference, emaciation (BMI < 18.5 kg/

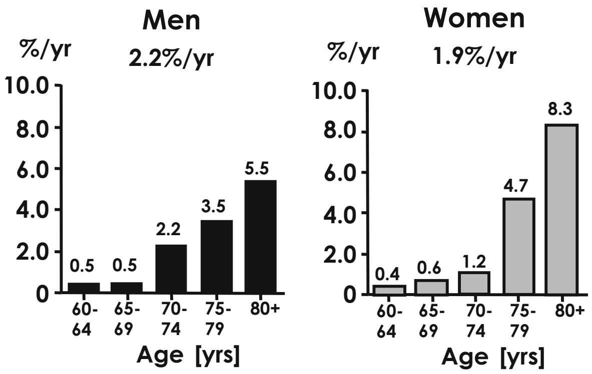

Fig. 2 Cumulative incidences (%/year) of sarcopenia stratified by age and sex

m^2), smoking habit, and alcohol drinking habit, logistic regression analysis revealed that the presence of OP was a significant predictive factor for SP occurrence in the near future (odds ratio, 2.99; 95% confidence interval, 1.46–6.12; $p = 0.003$; Table 4 (A)). This tendency was shown for both men and women when the logistic analysis was performed using identical adjustment factors except for sex; although, the association in men was diluted (men: odds ratio 6.92, 95% confidence interval 0.86–55.66, $p = 0.069$; women: odds ratio 2.58, 95% confidence interval 1.16–5.73, $p = 0.020$).

By contrast, the logistic regression analysis revealed that the presence of SP was no longer a significant predictive factor for OP occurrence in the near future (odds ratio, 2.11; 95% confidence interval, 0.59–7.59; $p = 0.253$; Table 4 (B)).

Discussion

In the present study, using information from the second and third surveys of the population-based ROAD cohort, we clarified the prevalence and characteristics of SP in Japan. We found that the prevalence of SP was significantly higher in those with OP compared to in those without OP. In addition, the prevalence of OP was significantly higher in those with SP compared to in those without SP. In the 4-year follow-up between the surveys, we estimated the SP incidence and found that the presence of OP significantly increased the future risk of SP, but the presence of SP did not increase the future risk of OP.

In the present study, SP prevalence was estimated using the AWGS definition because previous prevalence estimates on this cohort were conducted before the publication of the AWGS definitions [19]. The previous prevalences were higher compared with those noted in the present study, which is most likely because of the differences in cutoff values between the EWGSOP and AWGS definition criteria. According to the EWGSOP criteria, low handgrip strength was defined as <30 kg in men and <20 kg in women [5], whereas those for the AWGS definition are <26 and <18 kg, respectively. However, because all of the participants in the ROAD study were Japanese, we decided that the AWGS criteria would better reflect the SP prevalence of the cohort.

Besides previous reports using the EWGSOP definition [19], few studies have estimated the SP prevalence in the Japanese population. Applying the SP prevalence rate obtained in subjects aged ≥60 years in the present study (8.2%) to the Japanese 2010 census data [30] would indicate that in Japan, approximately 3,700,000 people (1,200,000 men and 2,500,000 women) aged ≥60 years might be affected by SP. Furthermore, in the present report, the degree of co-existence of SP and OP in those aged ≥60 years was clarified. The majority of patients with SP had OP, but patients with OP did not always have SP. Therefore, individuals with SP should be assessed for the potential co-existence of OP. Furthermore, not only was the presence of OP associated with the presence of SP, and vice versa, but also subjects with SP tended to have low BMD, whereas those with OP tended to have low physical performance and low muscle mass. Therefore, not only prevalence but also elements assessed for the diagnosis of SP and OP showed significant associations.

Regarding stature, emaciation is a well-known feature of OP. In a meta-analysis of prospective cohorts from >25 countries, including baseline BMI data from 398,610 women with an average age of 63 years and a follow-up of 2.2 million person-years, Johansson et al. reported that a high BMI was a protective factor for most fragility fracture sites [31]. Moreover, we reported previously that fast bone losers have significantly lighter body composition compared with healthy subjects [32]. However, regarding SP, despite consideration of sarcopenic obesity [33, 34], the association of emaciation and SP has received little attention. In the present study, emaciation was significantly associated with both OP and SP. Additionally, in the present study, none of the individuals with SP were obese (BMI >27.5 kg/m^2). In an overview of sarcopenic obesity, Cauley stated that obesity was usually defined by a high BMI, but some studies have relied on percentage body or visceral fat [35]. The findings of the present study suggest that high BMI might not be associated with the existence of SP. The definition of sarcopenic obesity should be incorporated from the view of the prevention of severe health illness of the elderly, such as cardiovascular diseases.

Regarding SP incidence, few reports have estimated SP incidence in not only Japan but also worldwide. In the present study, the cumulative SP incidence in Japanese subjects aged ≥60 years was 2.0%/year. Using the age-sex SP incidence against the Japanese 2010 census data [31], this suggests that approximately 1,050,000 people (350,000 men and 700,000 women) aged ≥60 years become newly affected by SP each year. The cumulative SP incidence increased with age, but there were no

Table 3 Comparison of characteristics of the subjects at the second survey classified by the occurrence or non-occurrence of sarcopenia or osteoporosis during a 4-year follow-up

	Sarcopenia (population at risk, n = 735)			Osteoporosis (population at risk, n = 675)		
	Non-occurrence (n = 677)	Occurrence (n = 58)	p value	Non-occurrence (n = 624)	Occurrence (n = 51)	p value
Mean values (SD) and percentage of selected characteristics						
Age (years)	69.5 (6.3)	76.2 (6.0)	<0.0001	70.1 (6.7)	71.3 (6.1)	0.223
Female sex (%)	67.1	63.8	0.612	61.4	84.3	<0.001
Height (cm)	154.9 (8.4)	152.2 (8.9)	0.0217	155.4 (8.5)	151.2 (7.9)	0.0008
Weight (kg)	56.7 (9.5)	49.2 (6.8)	<0.0001	57.2 (9.5)	49.9 (6.9)	<0.001
BMI (kg/m^2)	23.6 (3.1)	21.2 (2.2)	<0.0001	23.6 (3.1)	21.8 (2.8)	0.0001
Emaciation (BMI < 18.5 kg/m^2; %)	4.0	6.9	0.290	2.7	11.8	0.001
Residing in a coastal area (%)	51.3	32.8	0.007	50.0	37.3	<0.001
Current smoking habit (%)	7.6	8.8	0.758	8.6	4.1	0.269
Current alcohol drinking habit (%)	33.0	29.3	0.567	34.9	24.0	0.117
Mean values (SD) of selected measurements for sarcopenia diagnosis						
Grip strength (maximum) (kg)	30.3 (8.4)	25.9 (6.9)	0.0003	30.4 (8.6)	25.9 (6.8)	0.0003
Usual walking time (m/s)	1.16 (0.24)	1.02 (0.19)	<0.0001	1.15 (0.25)	1.08 (0.21)	0.0789
Appendicular skeletal muscle mass adjusted by height (kg/m^2)	6.70 (0.97)	6.00 (0.65)	<0.0001	6.75 (0.97)	6.17 (0.68)	<0.0001
Prevalence of sarcopenia (%)	0.0	0.0	–	2.7	7.8	0.043
Measurements related to the presence of osteoporosis						
BMD (L2–4) (g/cm^2)	0.929 (0.194)	0.884 (0.214)	0.104	0.968 (0.176)	0.797 (0.137)	<0.0001
BMD (femoral neck) (g/cm^2)	0.651 (0.119)	0.119) 0.596 (0.125)	0.0008	0.668 (0.116)	0.556 (0.042)	<0.0001
Prevalence of osteoporosis (L2–4 or femoral neck; %)	16.3	39.7	<0.001	0.0	0.0	–

n number of subjects, *BMI* body mass index, *BMD* bone mineral density, *SD* standard deviation

significant differences in the SP prevalence or incidence rates according to sex.

We reported the cumulative OP incidence previously, using the 3-year follow-up data from the baseline to second ROAD study surveys [36]. In that study, we estimated that the annual cumulative OP incidences were 0.76%/year at the lumbar spine and 1.83%/year at the femoral neck. In the present study, the annual OP incidence of subjects aged ≥60 years, between the second and third surveys, was estimated to clarify any associations with SP. The incidence of lumbar spine L2–4 OP in female subjects aged ≥60 years who participated in the baseline to the second survey [35] was compared with that in the present study (1.06 vs. 0.84%/year, respectively; $p < 0.01$; data not published). Similarly, the incidence of femoral neck OP in female subjects between these studies was significantly lower between the second and third surveys (2.49 vs. 1.87%/year, respectively; $p < 0.001$; data not published). We did not compare the OP incidence in men because the numbers were too low to provide statistical power for a comparison. This comparison shows that the OP incidence rate in women might be decreasing, although the reasons for this are unknown. Observation of the ROAD cohort is ongoing, and changes in incidence rates will be clarified after completion of the 10-year follow-up.

Finally, the logistic regression analysis revealed that the presence of OP significantly increased the risk of SP occurrence within 4 years. By contrast, the presence of SP did not predict OP occurrence within 4 years. However, as we noted, there was a significant proportion of patients with co-existent SP and OP (so-called 'osteosarcopenia'), suggesting that individuals with SP should be assessed for the presence of OP.

There are several limitations to the present study. First, although the ROAD study includes a large number of participants, the participants in the present study (second survey, individuals from the mountainous and coastal regions only) may not be completely representative of the general population. To address this issue, we compared the anthropometric measurements between the present study participants and the general Japanese population. The values for the general population were obtained from

Table 4 Mutual associations between the occurrence and presence of sarcopenia and osteoporosis

Logistic regression model				
Objective variable	Reference			
A. Effect of the presence of osteoporosis on sarcopenia occurrence				
Sarcopenia occurrence	0: no, 1: yes			
Explanatory variables	Reference	OR	95% CI	*p* value
Osteoporosis presence at the lumbar spine L2–4 or femoral neck	0: no, 1: yes	2.99	1.46–6.12	0.003
Adjusted factors				
Age (years)	1+ year	1.18	1.12–1.25	<0.001
Sex	0: men, 1: women	0.81	0.38–1.72	0.582
Residing area	0: mountainous area, 1: coastal area	0.45	0.24–0.85	0.013
Emaciation (BMI < 18.5 kg/m^2; %)	0: no, 1: yes	1.37	0.40–4.67	0.618
Current smoking habit	0: ex or never smoker, 1: current smoker	1.93	0.66–5.62	0.229
Current alcohol drinking habit	0: ex or never drinker, 1: current drinker	0.86	0.43–1.72	0.666
B. Effect of presence of sarcopenia for the occurrence of osteoporosis				
Osteoporosis occurrence at the lumbar spine L2–4 or femoral neck	0: no, 1: yes			
Explanatory variables	Reference	OR	95% CI	*p* value
Sarcopenia presence	0: no, 1: yes	2.11	0.59–7.59	0.253
Adjusted factors				
Age (years)	1+ year	1.03	0.98–1.08	0.280
Sex	0: men, 1: women	3.48	1.46–8.28	0.005
Region	0: mountainous area, 1: coastal area	0.51	0.27–0.85	0.033
Emaciation (BMI < 18.5 kg/m^2; %)	0: no, 1: yes	5.14	1.80–14.68	0.002
Current smoking habit	0: ex or never smoker, 1: current smoker	0.69	0.15–1.94	0.636
Current alcohol drinking habit	0: ex or never drinker, 1: current drinker	0.92	0.44–1.94	0.832

OR odds ratio, *95%* CI 95% confidence interval, *BMI* body mass index

the report on the 2008 National Health and Nutrition Survey conducted by the Ministry of Health, Labour, and Welfare, Japan [37] when the second ROAD survey began. For mean BMI, there were no significant differences between the second ROAD survey participants and the Japanese general population. In addition, among lifestyle factors, the proportion of current smokers and drinkers (those who regularly drink more than one drink/month) in the Japanese general population was compared with that in the present study population. The proportion of current smokers was lower in males in the present study population compared with the general Japanese population, but there was no significant difference in the number of female smokers (men, 19.1 vs. 25.6%, $p < 0.01$; women, 3.1 vs. 4.0%, $p = 0.28$). Moreover, the proportion of current drinkers was significantly lower in both men and women in our study population compared with the general Japanese population (men, 58.9 vs. 64.7%, $p < 0.05$; women, 16.0 vs. 21.0%, $p < 0.01$), suggesting that compared to the general Japanese population, the participants of the present study lead healthier lifestyles, at least in terms of smoking habits. This selection bias should be taken into consideration when generalizing the results obtained from the present study. Second, in the present study, handgrip strength, and 6-m walking tests were measured only once. Therefore, we could not exclude the effect of incidental changes in participants' performance around the examination date. Recurrent measurements should be taken into consideration to minimize fluctuation of measurements. However, we confirmed that none of the participants harbored hand or knee injuries that could have affected the measurements. Third, in the present study, OP was defined by BMD values using DXA alone. We might have to include participants who started medication for OP and/or those who developed new fractures. Although we had information regarding the medication and history of fractures, they were obtained from the self-report questionnaire leading to the possibility of recall bias. Therefore, in the present study, the incidence of OP might be underestimated. After the confirmation of medication by the interviewer, and assessment of fractures diagnosed by radiographic examinations performed in the ROAD study, the cumulative incidence of OP should be revised. Finally, the 4-year follow-up period might be too short to determine the causal relationship between SP and OP. Only a small number of new OP and SP cases occurred during the 4-year observation period. However, the ROAD study continues, so determining the occurrence of OP and SP over an extended period will be possible in the future, enabling the validation of the causal relationship between SP and OP using the incidence rate, rather than cumulative incidence as an epidemiological index.

In conclusion, the prevalence of co-existing SP and OP were high, suggesting that subjects ≥60 years with SP should be assessed for concomitant OP. Moreover, the presence of OP was significantly associated with SP occurrence within 4 years. Therefore, treatment for OP might not only have clinical benefit for the treatment of OP itself but might also reduce the risk of subsequent SP development.

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Compliance with ethical standards

Conflicts of interest None.

Ethical approval All participants provided written informed consent, and the study was conducted with the approval of the ethics committees of the University of Tokyo (Nos. 1264 and 1326) and the University of Wakayama Medical University (No. 373). All procedures were conducted in accordance with the ethical standards as described in the 1964 Declaration of Helsinki, and its later amendments.

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Association of Lumbar Spondylolisthesis with Low Back Pain and Symptomatic Lumbar Spinal Stenosis in a Population-basedCohort: The Wakayama Spine Study

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ABSTRACT

Study Design

Cross-sectional study

Objective

To determine the association between lumbar spondylolisthesis and low back pain and symptomatic lumbar spinal stenosis (LSS)in a population-based cohort.

Summary of Background Data

The basic epidemiology of lumbar spondylolisthesis is not well known. There is little information regarding the association between lumbar spondylolisthesis and clinical symptoms such as low back pain and LSS symptoms.

Methods

This cross-sectional study included data from 938 participants (308 men, 630 women; mean age, 67.3 years; range, 40–93 years). Lumbar spondylolisthesis was defined as a slip of ≥5%. Diagnostic criteria for symptomatic LSS required the presence of both leg symptoms and radiographic LSS findings on magnetic resonance imaging. The prevalence of low back pain and symptomatic LSS was compared between those with or without spondylolisthesis.Furthermore, we determined the association between the amount of slippage and presence of symptomatic LSS.

Results

The prevalence of spondylolisthesis at any level was 15.8% in the total sample, 13.0% in men, and 17.1% in women; the prevalence was not significantly different between men and women ($P = 0.09$). In both, men and women, symptomatic LSS was related to spondylolisthesis (odds ratio [OR]: 2.07; 95% CI: 1.20–3.44); however, no such association was found for spondylolisthesis and presence of low back pain.The amount of slippage was not related to the presence of symptomatic LSS ($P= 0.93$).

Conclusions

This population-based cohort study revealed that lumbar spondylolisthesis had a closer association with leg symptoms than with low back pain. There was a significant difference in the presence of symptomatic LSS between participants with and without spondylolisthesis. However, the amount of slippage was not related to the presence of symptomatic LSS.

Keywords: lumbar spondylolisthesis, lumbar spinal stenosis, low back pain, magnetic resonance imaging, population-based cohort

Level of evidence: 3

Introduction

Lumbar spondylolisthesis is a disorder that causes one vertebral body to slipover the one below, withtwo main etiologies: spondylolytic and degenerative[1]. Despite the considerable number of surgeries performed for spondylolisthesis[2, 3], the epidemiology of lumbar spondylolisthesis is not well known. To the best of our knowledge, there are 4 reports on the prevalence of lumbar spondylolisthesis in the general population[4-7], including a study in Asia with 1242 urban taxi drivers in Taiwan, of whom 96% were men[4], anda study in Denmark that involved subjects of both the sexes[5].The prevalence of lumbar spondylolisthesis differs greatly among these reports, ranging from 3–31%in men [4-6] and 6–29%in women [5, 7]; this wide variation may be relatedto regional variancesand different sample sizes.

It is believed thatlumbar spondylolisthesis is a frequent cause of low back pain and leg symptoms. Although low back pain and neurogenic leg symptomswere originally considered to be the principal symptoms of lumbar spondylolisthesis, there is little information regarding the association between clinical symptoms and spondylolisthesis, withdiffering results in previous studies [5,7,8]. A relationship between posterior spondylolisthesis at L3 and low back painin white elderly women has been reported[7], while other reports concluded that the correlation was not as strong as expected[5,8]. In these studies, symptomswere assessed using a questionnaire; however, a specialist's clinical impression is needed forLSS diagnosis.We previouslyreported the prevalence of low back pain and symptomatic LSSin an elderly cohort,diagnosed by an orthopedic surgeon [9,10]. For symptomatic LSS, magnetic resonance imaging (MRI)finding that were consistent with the symptoms were confirmed.

The present study aimed to determine the epidemiological data, including the prevalence and distribution, for lumbar spondylolisthesisaccording to age andsexin the general population using the baseline survey of The Wakayama Spine Study as well asto evaluate the association oflumbar spondylolisthesis with low back pain and symptomatic LSS using mobile MRI in a population-based cohort.

Materials and Methods

Participants

The present study, entitled The Wakayama Spine Study, assessed a subcohort from the Research on Osteoarthritis/Osteoporosis Against Disability (ROAD) study, which is a large-scale, prospective study of bone and joint diseases among population-based cohorts established in several communities in Japan. As the detailed profile of the ROAD study is described elsewhere, only a brief summary is provided here[11-14]. A database including baseline clinical and genetic information for 3,040 inhabitants (1,061 men, 1,979 women) with a mean age of 70.6 years (range, 23–95 years) was created. We recruited individuals listed in resident registrations in 3 communities: an urban region in Itabashi, Tokyo; a mountainous region in Hidakagawa, Wakayama; and a coastal region in Taiji, Wakayama. All participants provided written, informed consent, and the study was conducted with the approval of the ethics committees of the University of Tokyo and the Tokyo Metropolitan Institute of Gerontology. Participants completed an interviewer-administered questionnaire that consists of 400 questions including those for lifestyle, and they underwent anthropometric measurements and assessments of physical performance. Blood and urine samples were collected for biochemical and genetic examinations. The ankle-brachial index (ABI) was measured for all participants. (OMRON Co.,Kyoto, Kyoto, Japan)

The ROAD study team made a second visit to Hidakagawa and Taiji, and the inhabitants who provided written, informed consent for the MRI examination were registered in the Wakayama Spine Study. Participants who had sensitive implanted devices (e.g., pacemaker), claustrophobia, or other contraindications were excluded, and 977 participants underwent the lumbar spine MRI in a mobile MRI unit (Excelart 1.5 T; Toshiba; Tokyo, Japan). Ten participants who underwent a previous lumbar operation for LSS were excluded, and 29 participants < 40 years old were excluded because LSS is a degenerative disease. Thus, MRI results were available for 938 participants (308 men, 630 women).

Assessment of spondylolisthesis

All participants underwent A-P and lateral radiographs of the lumbar spine, including intervertebral levels from L1-L2 to L5-S1. The %slip was calculated as the distance of sagittal translation between adjacent vertebral endplates. These lumbar spine radiographs were read without the knowledge of participant clinical status by a well-experienced orthopedic surgeon (YI).

A diagnosis of spondylolisthesis was established when %slip was ≥5% in the lateral views.Inter- and intra-observer reproducibility were assessed by having both the raters (YI, SM) independently evaluate spondylolisthesis on 150 levels of L3–L5 slipping from 50 randomly chosen images. The kappa statistic was computed as the measure of agreement. Both inter- and intra-observer agreements were excellent with respect to the presence of lumbar spondylolisthesis, with kappa values of 0.83 and 0.85, respectively.

Assessment of low back pain and symptomatic lumbar spinal stenosis

An experienced orthopedic surgeon (YI) collected the medical history and performed the physical testing for all the participants[9,10]. Under medical history, information aboutthe presence of low back, buttock, and leg pain; area of pain or otherdiscomfort;and presence of intermittent claudication and its distance was collected; and themodified Zurich Claudication Questionnaire (excluding six items about satisfaction and history of lumbar surgery for symptomatic LSS) was administered. Physical examinations included determination of the symptoms induced by lumbar extension;improvement or induction of symptoms with lumbar flexion; floor finger distance (cm); peripheral circulation, determinedby palpating the dorsalis pedis artery (good or poor); administration of thestraight leg raised test; manual muscle testing of both, the upper and lower extremities; tendon reflex testing for both, upper and lower extremities; and Babinski reflex testing.

Regarding low back pain, all participants were asked the following question by the same orthopedic surgeon: “In the past month, have you had pain that last on most days?”Those who answered “yes” were identified as having low back pain[11]. The diagnostic criteria for symptomatic LSS were based on the LSS definition from the North American Spine Society (NASS) guidelines[15].

The orthopedic surgeon (YI) established the diagnosis of LSS, which required one or more of the following symptoms that were induced or exacerbated with walking or prolonged standing and relieved with lumbar flexion, sitting, and recumbency: pain, numbness and neurological deficits in the lower extremities and buttocks, and bladder/bowel dysfunction. The severity of radiographic LSS was assessed qualitatively by a well-experienced orthopedic surgeon (YI). The severity of the central, lateral recess[16], and foraminal stenoses were rated as none, mild, moderate,or severe[17]; mild stenosis was defined as a maximum of 1/3 narrowing of the normal area, moderate stenosis as a 1/3 to 2/3 narrowing, and severe stenosis as more than 2/3 narrowing.[10]A diagnosis of radiographic LSS required more than moderate severity and radiographic findings consistent with the symptoms.

The same experienced orthopedic surgeon (YI) made the final diagnosis of symptomatic LSS, which required presentation of both, LSS symptoms and radiographic LSS. There were no participants with LSS symptoms due to tumor, inflammatory, or traumatic pathologies.

Statistical analysis

All statistical analyses were performed using JMP, version 8 (SAS Institute Japan; Tokyo, Japan). Differences in age, height, weight, and BMI between gendersas well as differences in the prevalence of spondylolisthesis based on age were examined using Student's *t*-tests. Chi-squared tests were used to compare low back pain and symptomatic LSS between genders,differences in spondylolisthesis based on radiographic LSS, and differences in low back pain based on backward slip at L3–4. Furthermore, logistic regression analysis was performed to determine ~~the~~the association of spondylolisthesis with symptomatic LSS, adjusted for age, gender, and BMI. To clarify the association between the amount of slippage and symptomatic LSS, we performed Student's *t*-test using anterior %slip of L4 (n = 86) and symptomatic LSS.

Results

Table 1 shows the demographic and clinical characteristics of the 938 participants (308 men and 630 women; mean age 67.3 years, range 40–93 years). Among the participants with symptomatic LSS (n =84), 5 presented with peripheral artery disease (ankle-brachial index<0.9). However, the leg symptoms of these 5 participants were dependent on position.

The prevalence of spondylolisthesis,including anterior and posterior at any level, was 15.8% in the total sample, 13.0% in men, and 17.1% in women; the prevalence of spondylolisthesis was not significantly different between the genders(P=0.09) (Figure 1). Spondylolisthesis was observed at L3/4, L4/5, and L5/S1, with the greatest prevalence at L4/5 in both genders (men, L3/4: 3.6%; L4/5: 7.5%; L5/S: 3.2%;women, L3/4: 4.5%; L4/5: 10.3%;L5/S: 2.9%).Only one vertebral level was involved in 95.3% of the participants with spondylolisthesis.Of the participants with spondylolisthesis, 16 had backward slip, with the majority at L3/4 (L3/4,n = 15; L4/5, n = 2; L5/S, n =

0). The presence of low back pain was notsignificantly different between those with and without backward slip at L3-4 (low back pain with backward slip at L3-4: 48.7% [19/39]; low back pain without backward slip at L3-4: 39.2% [352/899]; P= 0.23).

Bothgenderswith spondylolisthesis were more likely to have low back pain than those without spondylolisthesis, but this was not significant (men,P=0.55; women,P=0.11; Table 2). Theprevalence of symptomatic LSS wassignificantlyhigher in those with than in those without spondylolisthesis in both genders. The prevalence of symptomatic LSSin men with spondylolisthesis wasapproximately 3 times of that withoutspondylolisthesis.In the logistic regression analysis adjusted for age, sex, and BMI, spondylolisthesis was the significant risk factor for symptomatic LSS (odds ratio [OR]: 2.07;95% CI: 1.20–3.44).

The mean anterior L4%slipin the total sample was 14.1±4.3%, in participants with symptomatic LSS was 14.1±1.2%, and in participants without symptomatic LSS was 14.1±0.5%. There was no significant difference in the mean anterior L4% slip between symptomatic LSS and no symptomatic LSS (P=0.93).

Discussion

In this study, the prevalence of spondylolisthesis at any level was 15.8% in the total sample, 13.0% in men, and 17.1% in women; the difference between the genders was not significant. There were only 6 participants<50 years old with spondylolisthesis, and spondylolisthesis was observed with the greatest prevalence at L4/5 (59.5%). Spondylolisthesis was significantly associated withsymptomatic LSS, but not with low back pain. Furthermore, the mean L4% slip was not related tothe presence of symptomatic LSS.

As already mentioned, the prevalence of spondylolisthesis in previous studies varies (4-7): 3–31% in men and6–29% in women. Denard et al. [6]reported that the prevalence in 300 men recruited from 5,995 participants aged ≥65 years was 31% in the Osteoporotic Fractures in Men Study; however, it is widelyconsidered that the prevalence in women is significantly higher than that in men.The lack of a significant difference in the prevalencebetween genders in the present study might be related to the anatomical differences in the different racial groups;to the best of our knowledge, no other study has reported the prevalence of lumbar spondylolisthesisin the general populationof Japan.

In the present study,lumbar spondylolisthesis was not relatedto low back pain. Similarly,no relationship between spondylolisthesis and low back pain has beenreported. In The Copenhagen Osteoarthritis Study, which included 1533 men and 2618 women, degenerative spondylolisthesis assessed using computed tomography was not significantly associated with low back pain assessed using a questionnaire[5].In the Pittsburgh clinic of the Multicenter Study of the Osteoporotic Fractures, which included 788 white elderly women, only retrolisthesis at L3-4 was associated with low back pain[7].However, lumbar spondylolisthesis induces degenerated and subluxated facet joints, and segmental instability might cause tension of the facet joint capsule and ligaments.Therefore, the development ofspondylolisthesis mightbe related to low back symptoms; however,few studies have been conducted regarding the association between the development of spondylolisthesis and low back pain. In a 25-year longitudinal study in Framingham, which included 617 subjects, the development of degenerative lumbar spondylolisthesis was significantly related to low back pain [18]. However, because of the long follow-up period, the authors were unable to determine when spondylolisthesis or low back painoccurred or worsened. Further surveys of the Wakayama Spine Study thatare planned for 3-year intervals will help to clarify the association between progressivespondylolisthesis and low back symptoms.There are multiple factors associated with the occurrence of low back pain; therefore, we also aim to identify other contributing factors such as spinal stenosis, scoliosis, facet osteoarthritis,anddisc degeneration.

In the present study, the prevalence of symptomatic LSSwas significantly higher in those with than in those withoutspondylolisthesis, however, %slipof L4 was not related with the presence of symptomatic LSS. Lumbar spondylolisthesis has traditionally been considered a major cause of leg symptoms in LSS. However, previous studies have not been conducted regarding the association between lumbar spondylolisthesis and symptomatic LSS with a diagnosisbased on the presentation of both LSS symptoms and radiographic LSS; an association between lumbar spondylolisthesis and leg symptoms has been reported, although the leg symptoms were not diagnosed by a specialist and not confirmed using MRI.Radicular pain and lower extremity weaknessassessed using questionnaires occurred more frequently in men with spondylolisthesis thanin men without spondylolisthesis[8], and no relationship between any qualities of low back pain, including gluteal or radicular pain, and degenerative spondylolisthesis has also been reported[5].While the amount of slippage is of clinical concern because it can cause spinal stenosis and nerve root compression, the present study demonstrated that %slip was not related to the presence of symptomatic LSS. However, it is possible that the amount of slippage is related with the severity of clinical symptomsas well as the natural history of clinical symptoms, which will be explored in our longitudinal study.

There were several limitations of the present study. First, the participants were not randomly selected;however, approximately 1000 participants were included, and no significant differences in BMI were found between the participants and the general Japanese population (men: 23.71 [3.41] vs. 23.95 [2.64] kg/m^2; women: 23.06 [3.42] vs. 23.50 [3.69] kg/m^2)[19]. Hence, we think that the participants can represent the general Japanese population. The proportions of current smokers and drinkers (men) and current drinkers (women) were significantly higher in the general Japanese population than in the study population (smokers: men, 32.6% vs. 25.2%; women, 4.9% vs. 4.1%; drinkers: men, 73.9% vs. 56.8%; women, 28.1% vs. 18.8%), suggesting that the study participants likely led healthier lifestyles than the general Japanese. Second, conclusive evidence of any causal relationship could not be determined because this was a cross-sectional study. Third, this study investigated elderly participants who lived independently rather than those who lived in institutional settings, potentially resulting in underestimated prevalences. Finally, the exclusion of 10 subjects who already had surgery for LSS could have influenced the results.

Nevertheless, this is the first study to evaluate the association betweenlumbar spondylolisthesis and symptomatic LSS in the general population using MRI. In addition, the Wakayama Spine Study is a longitudinal survey; therefore, future results will help elucidate any causal relationships.

In conclusion, we described the prevalence of lumbar spondylolisthesis and its association with low back pain and symptomatic LSS. Lumbar spondylolisthesis more related to leg symptoms than low back pain. Although spondylolisthesis was significantly related with the presence of symptomatic LSS, the amount of slippage was not associated with symptomatic LSS.

Acknowledgments

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Figure 1. Prevalence of lumbar spondylolisthesis classified by age and gender from a community cohort in Japan

Fig. 1

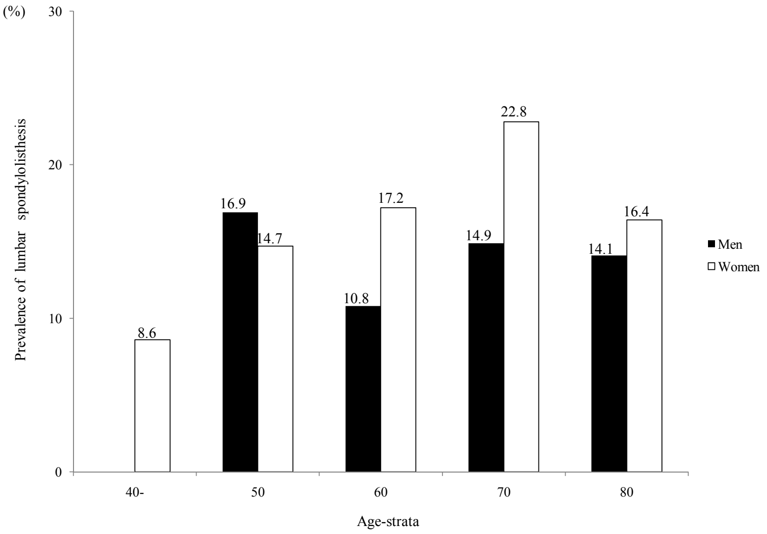


Fig. 1. Prevalence of lumbar spondylolisthesis classified by age and gender from a community cohort in Japan.

Table 1. Characteristics of participants

	Total	Men	Women
No. of participants	**938**	**308**	**630**
Age group (years)			
<49	96	26	70
50–59	175	59	116
60–69	222	65	157
70–79	258	87	171
≧80	187	71	116
Demographic characteristics			
Age, years	67.3 ± 12.4	68.3 ±12.5	66.9 ± 12.3
Height, cm	155.7 ± 9.3	164.4 ± 6.9**	151.4 ± 7.1
Weight, kg	56.7 ± 11.4	64.3 ± 11.3**	53.0 ± 9.4
Body mass index, kg/m^2	23.3 ± 3.6	23.7 ± 3.3*	23.1 ± 3.6
The state of participants			
Low back pain	371	111	260
Symptomatic LSS	84	29	55

LSS means lumbar spinal stenosis. A non-paired Student' s *t* test was used to determine differences in demographic characteristics between men and women. Chi-square test was used to determine differences in low back pain and symptomatic LSS between men and women. Values are the means ± standard deviation. * $p<0.05$, ** $p<0.01$,

Table2. Prevalence of low back pain and symptomatic LSS among spondylolisthesis or non-spondylolisthesis

	Low back pain			Symptomatic LSS		
	Total (N=371)	**Men (N=111)**	**Women (N=260)**	**Total (N=84)**	**Men (N=29)**	**Women (N=55)**
Spondylolisthesis (N=148)	69/148 (46.9%)	17/40 (42.5%)	52/108 (48.2%)	23/148** (15.5%)	8/40* (20.0%)	15/108* (13.9%)
Non-spondylolishesis (N=790)	302/790 (38.2%)	94/268 (35.1%)	208/522 (39.9%)	61/790 (7.2%)	21/268 (7.8%)	40/522 (7.7%)

Chi-square test was used to determine differences in low back pain and neurogenic claudication between spondylolisthesis and non-spondylolisthesis. *p<0.05 **p<0.01

LSS means lumbar spinal stenosis.

Ⅴ. 資料

あなたは大丈夫？ L4/5の腰痛借金！

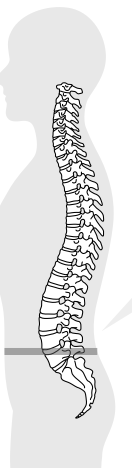
「これだけ体操」ですぐに返済！

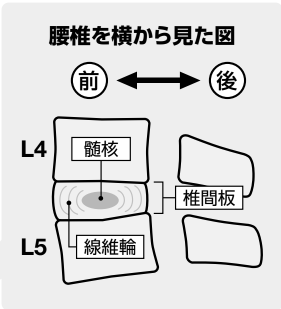
一番負担がかかるのは、4番目と5番目の腰骨の間（L4/5椎間板）なのです！

腰痛借金って、なんですか？

●腰痛借金の無い状態

背骨と背骨にはさまれた椎間板の中には、ゼリー状の髄核（ずいかく）という物質があります。
髄核は線維輪（せんいりん）という硬い組織に囲まれており、通常、椎間板の中央に位置しています。
そして、これが腰痛借金の無い状態です。

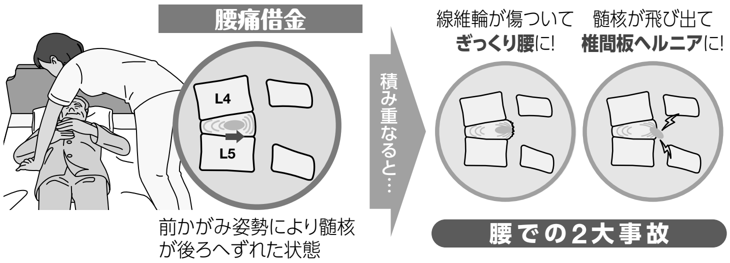




L4/5はウエストライン（ベルトの位置）にあります

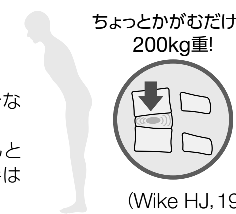
●腰痛借金と、腰痛借金が呼び込む2大事故

髄核は、通常は椎間板の中央にありますが、前かがみでの仕事を続けていると後ろ（背中側）に移動します。これが腰痛借金のある状態です。
この腰痛借金が積み重なると、髄核が後ろへずれっぱなしとなり、ぎっくり腰やヘルニアといった腰での2大事故が起きる可能性が高くなってしまうのです。



ちょっとした不良姿勢に忍び寄る腰痛借金の魔の手?!

椎間板には、普段の何気ない動作でも思いのほか大きな力が加わっています。
少し前へかがむだけでも、L4/5の椎間板にはなんと200kg重もの力が加わっており、腰痛借金の魔の手はちょっとした不良姿勢にも忍び寄っているのです。



（Wike HJ, 1999）

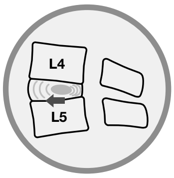
借金はその場で返済！ 「これだけ体操」で腰痛予防！

●どうやるの？

息を吐きながら、3秒間 腰を反らすだけ（1〜2回）

手の指先を下にしてお尻に当て、骨盤を前へ押し出すイメージで腰の下のほう（骨盤のすぐ上）ともものの付け根を同時にストレッチします。

腰痛借金の返済



後ろにずれた髄核を、腰を反らして元の位置に戻す

腰に親指をかけて腰だけを反らすのはNGです！
（特に反り腰姿勢の方は注意）

足は肩幅より少し広めに開く

このときは中止！

痛みがお尻から太もも以下に響く場合は中止し、整形外科医にご相談ください。

●効果はあるの？

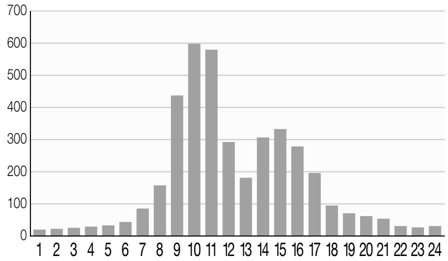
はい、「これだけ体操」を実践し続けた介護施設では、実施しなかった施設に比べ、明らかに「腰痛持ち」が少なくなったという結果が得られています。

（Matsudaira K, 2015）

●いつやればいいの？

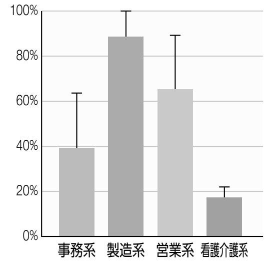
職場でのぎっくり腰は、身体反応の低下している午前中、次に昼休憩後の14〜15時に発生しやすいことがわかっています。一方、職場の始業時体操実施率をみると、他業種に比べ介護・看護系が著しく低いことが報告されています。

職場での「ぎっくり腰」の時間別発生状況（n=4,008）



（厚生労働省, 2013）

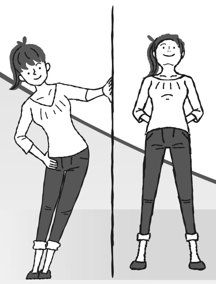
職種別始業時体操実践率（n=1,206）



（高野, 2015）

以上のことから、「これだけ体操」は、次のように行うとよいでしょう。

STEP 1 朝の始業時に毎日みんなで実施（朝の貯金）
STEP 2 各自、昼休憩時に実施（昼の貯金）
STEP 3 作業に応じて、その都度、腰痛借金をチャラにする！



腰痛予防 これだけ体操®

腰が痛いときの安静のしずぎに注意しましょう。

「安静がいちばん」はもう古い!!!
腰痛の研究が飛躍的にすすみ、安静にしすぎないことが、世界的に治療の常識になりました。

東京大学医学部付属病院22世紀医療センター
運動器疼痛メディカルリサーチ&マネジメント講座
特任教授
http://www.lbp4u.com 松平　浩

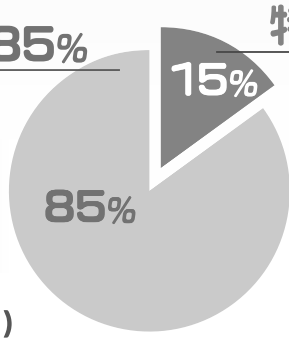
腰痛の種類

腰痛は、「病気が原因の腰痛（特異的腰痛）」と「検査や診断でも痛みの原因がはっきりしない腰痛（非特異的腰痛）」の2種類に別けられます。腰痛で受診する人の85%が原因のはっきりしない非特異的腰痛です。これには慢性的な腰痛やぎっくり腰なども含まれます。

非特異的腰痛 85%

検査や診断でも痛みの原因がはっきりしない腰痛

腰痛の代表格
- ぎっくり腰
- 慢性的腰痛
- 再発を繰り返す腰痛



特異的腰痛 15%

病気が原因の腰痛

医療機関で検査を受けてください

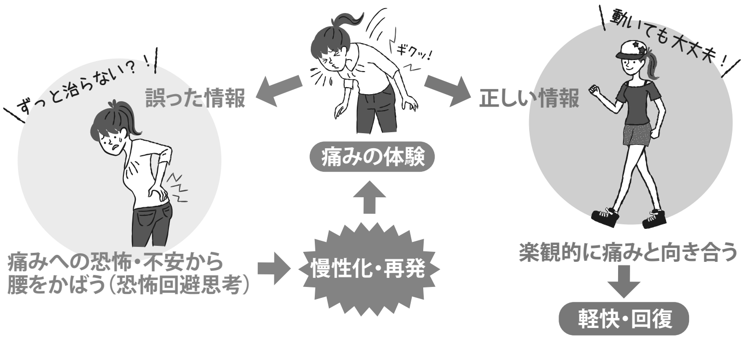
腰痛の代表格
- 椎間板ヘルニア ● 脊柱管狭窄症 ● 骨折

命にかかわる腰痛
- がん ● 大動脈瘤 ● 感染

これだけ体操で緩和（裏面へ）

痛みを恐れて安静にしすぎると治りにくい

- 適度に体を動かさないと、背骨や周辺の筋肉の柔軟さが失われます。
- 筋肉が酸素不足となり発痛物質が分泌されます。



腰痛への不安や恐怖は、痛みを抑制する脳の機能を低下させます。
「怖くない」と自分に言い聞かせましょう。

当てはまっていたら要注意！！

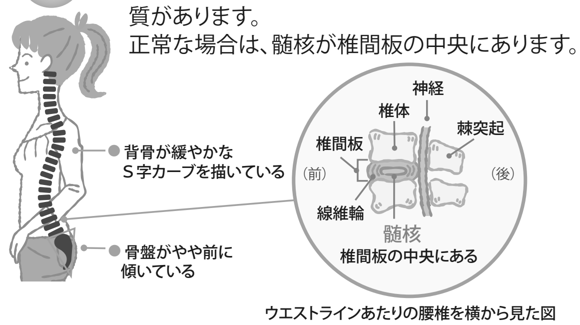
1つでも当てはまれば、
腰痛の原因が病気によるものかもしれませんので、
医療機関で検査を受けてください。

- 転んだりした後に痛みだし、日常生活に支障がでる。
  →骨折の疑い
- 65歳以上で（特に女性）で、朝、布団から起き上がるときに腰や背中に痛みが出た。
  →骨粗しょう症による骨折の疑い
- 横になってもうずく。鎮痛剤を一か月以上使用しても痛みが改善されない。
  →重い病気の疑い
- 痛みやしびれがお尻からひざ下まで広がる。
  →腰部脊柱管狭窄症・椎間板ヘルニアの疑い
- 肛門、性器周辺が熱くなる、しびれがある。尿が出にくい。尿漏れがある。
  →重症な腰部脊柱管狭窄症・椎間板ヘルニアの疑い
- つま先歩き、かかと歩きが難しく、足の脱力がある。
  →重症な腰部脊柱管狭窄症・椎間板ヘルニアの疑い
  脳や脊髄の病気の疑い

腰痛の原因

正常

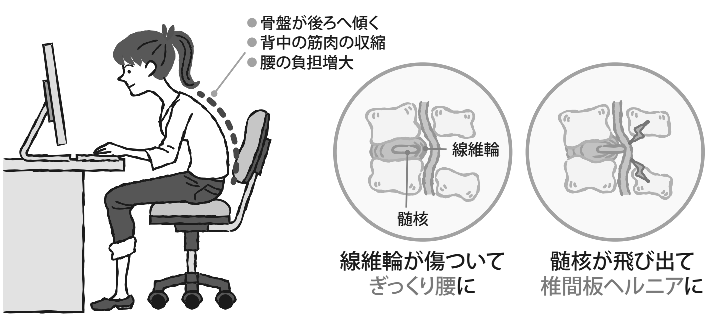
背骨と背骨のあいだの椎間板の中に、硬い組織に囲まれたゼリー状の髄核（ずいかく）という物質があります。
正常な場合は、髄核が椎間板の中央にあります。



ウエストラインあたりの腰椎を横から見た図

腰痛

前かがみでの作業、猫背の姿勢が続くと髄核が後ろ（背中側）に移動します。この状態が続くと「ぎっくり腰」や椎間板ヘルニアになります。



線維輪が傷ついて
ぎっくり腰に

髄核が飛び出て
椎間板ヘルニアに

（一社）新潟県労働衛生医学協会　http://www.niwell.or.jp/
〔第1版〕H29.0 00,000

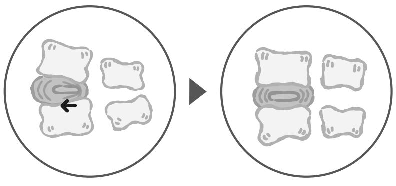
腰痛予防 これだけ体操®

これだけ体操 腰を反らす

最重要！

こんなとき
座り作業で前かがみが続いたとき、
重い荷物を持ったあとなど

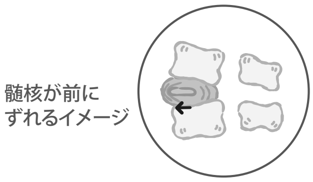
❶足を肩幅よりやや広めに平行に開き、両手を支点に腰をしっかり反らす。
❷息を吐きながら最大限に反らした状態を3秒間保つ(1〜2回)。

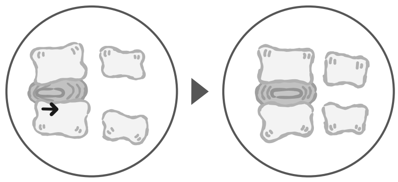


これだけ体操 腰をかがめる

こんなとき
ヒールで立ち仕事の多い
女性や妊婦の方向け

長時間立ったり歩いたりして腰に
反りぎみの負荷がかかったとき



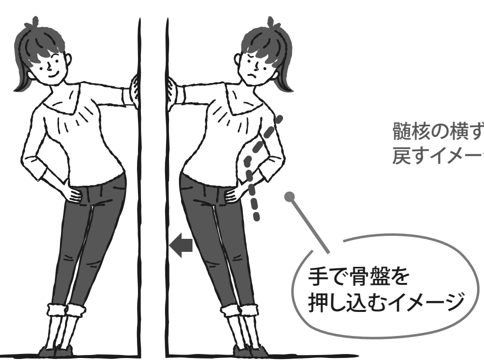


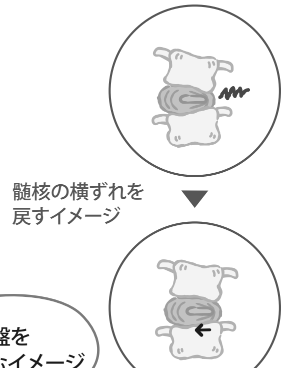
❶椅子に腰かけ、足を肩幅より広めに開く。
❷息を吐きながら、ゆっくり背中を丸め、床を見ながら3秒間姿勢を保つ(1〜2回)。

これだけ体操 腰を横に曲げる

こんなとき
腰の左右どちらかに違和感があるとき

❶足元が滑らない場所で、安定した壁から離れて立つ。
❷肩の高さで手掌から肘までを壁につき、腰を横に曲げる。左右行う。
❸違和感を感じて曲げにくい側があれば、その方向に、ゆっくりと息を吐きながら徐々に曲げ、きついと感じるところまでしっかり曲げる。
❹左右差がなくなるまで繰り返す(5秒を3〜5回が目安)。





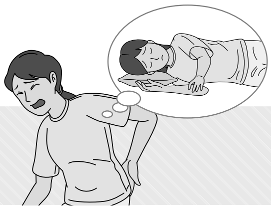
こんなときは
中断しましょう

痛みがお尻から太もも以下に響く場合は中止し、整形外科医にご相談ください。

(一社)新潟県労働衛生医学協会　http://www.niwell.or.jp/
〔第1版〕H29.0 00,000

職場の腰痛対策マニュアル

知っていましたか？ 腰痛の新常識



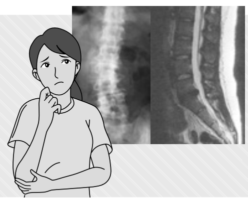
腰痛がある時は「とりあえず安静」と思っていませんか？

新常識

伝統的にはそうですが、明らかな原因疾患のない一般的な腰痛*（言いかえれば心配のない腰痛）に対しては、今や予防としても治療としても世界的に「安静」は薦められていません！

＊明らかな原因疾患のある腰痛（**特異的な腰痛**）としては、神経痛を伴う椎間板ヘルニア、腰骨の腫瘍や感染、骨折などが挙げられます（下の「**これは注意!病院で診てもらったほうがよい特異的な病気の潜在を疑う随伴症状**」を参照）。ただその割合は少なく（病院にかかる人のうちでもわずか1%くらい）、腰痛のほとんどが原因疾患のないもので、**非特異的な腰痛**と総称されます。

- 「ぎっくり腰」でさえも、安静を保ち過ぎるとかえってその後の経過がよくないことがわかっており、お仕事を含む普段の活動をできる範囲で維持したほうが望ましいとされています。



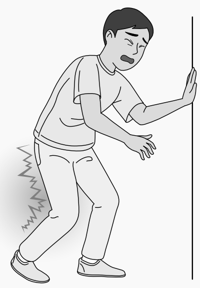
レントゲンやMRIの所見をみて、「変形している」「椎間板がつまっている（傷んでいる）」「ずれがある」「ヘルニアがある」「分離症がある」などと言われると、これらが腰痛の原因と思ってしまいませんか？

新常識

画像所見のほとんどは腰痛の原因を説明できません。
また、今後腰痛で困り続けるかどうかの判断材料にもならないことが多いのです。よって腰の画像所見をネガティブイメージで指摘されても、**悲観する必要はありません！**

- ヘルニア像も含めこのような所見は、腰痛があろうがなかろうが、少なくともどれか一つは多くの人にみられます。逆に腰痛持ちでも画像に全く異常所見がない人もいます。
- 椎間板に負担がかかっている所見は、20代からみられることも珍しくありません。

これは注意！ 病院で診てもらったほうがよい特異的な病気の潜在を疑う随伴症状



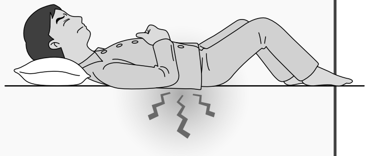
背骨の神経の病気（椎間板ヘルニアや脊柱管狭窄症など）を疑う症状

おしりを含む脚（足）に痛みやしびれ（特に膝を超えて放散するもの）を伴っていると、椎間板ヘルニアや脊柱管狭窄症を疑う必要があります。

非常に稀ではあるが、危険な痛みを疑うサイン

最も重要なことは、**脊椎の感染や腫瘍、大動脈瘤、など命にもかかわりうる危険な病気を疑うサインがある場合には**、「忙しいから」「きっと筋肉痛だから」と言ってほったらかしにしないことです。
以下の兆候があるならば、早急に病院での精密検査を念のため受ける必要があります。

- 腰を動かさなくじっとしていても痛い、夜間等横になっていても痛みが楽にならない
- 微熱でも発熱が続いている
- 体調がすぐれない（冷や汗、動悸、倦怠感など）
- 最近理由もなく体重が減ってきた
- 癌や結核を患ったことがある
- 数値がうまくコントロールされていない糖尿病や高血圧がある
- 鎮痛薬を1ヵ月近く服用しているにもかかわらず頑固な痛みが続いている



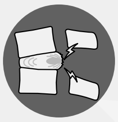
仕事に支障をきたす 腰痛が起こったり長引いたりする危険因子は?

1 従来から指摘されている介護作業や運搬といった持ち上げ動作や前屈み動作が頻繁な作業に関わっていることが、重要な危険因子であることは間違いありません。

腰自体の不具合?
それとも脳機能の不具合?
その見極めは?

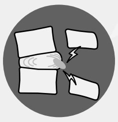
原因(メカニズム)

危険因子



椎間板が傷ついてぎっくり腰に!

腰での2大事故



髄核が飛び出して椎間板ヘルニアに!

積み重なると…

腰自体の不具合

＝

腰痛借金

前屈み姿勢により椎間板内にある髄核が後ろへずれた状態が腰痛借金のある状態です。

メカニカルな腰へのストレス

持ち上げ、前屈み、捻り、不良姿勢 など

- 姿勢・動作と腰痛の関係性が明確かつ一貫性がある
- 全く痛くない姿勢が必ずある

不活動、姿勢バランスの乱れ

脳機能の不具合

心理的なストレス

周囲のサポート不足、仕事への不満、人間関係のストレス、痛みへの強い不安

- 普通そんな痛くないだろうという刺激で、すごく痛がる
- 睡眠障害、肩こり、胃腸の不調といった身体症状が複数ある、あちこち痛い

2 職場で人間関係のストレスがあることや周囲のサポートが少ないこと、仕事のやりがいが低いこと、腰痛に対する過剰な不安や恐れ感(恐怖回避行動)といった心理・社会面の問題も無視できない重要な因子であることがあきらかになっています。

2 脳機能の不具合への対策

対策① ストレスを逃がし、ドパミン、オピオイド、セロトニンが出にくくなるのを極力抑えること

イラッときたら右から左へ受け流し「不満ノート」で解消を!

セルフディスクロージャー
Tamir DI,Mitchell : Proc Natl Acad Sci USA 109: 8038-43, 2012

アクティブリスニング

対策② ドパミン、オピオイド、セロトニンを意識的に分泌させる対策を準備しておくこと

ドパミンの分泌を促す即効性の頓服薬は「ワクワク系の音楽」

Salimpoor VN, et al: Nat Neurosci 14: 257-62, 2011

ウォーキングと呼吸法でセロトニン分泌を促してみよう!

Fumoto M,et al: Behav Brain Res 213: 1-9, 2010

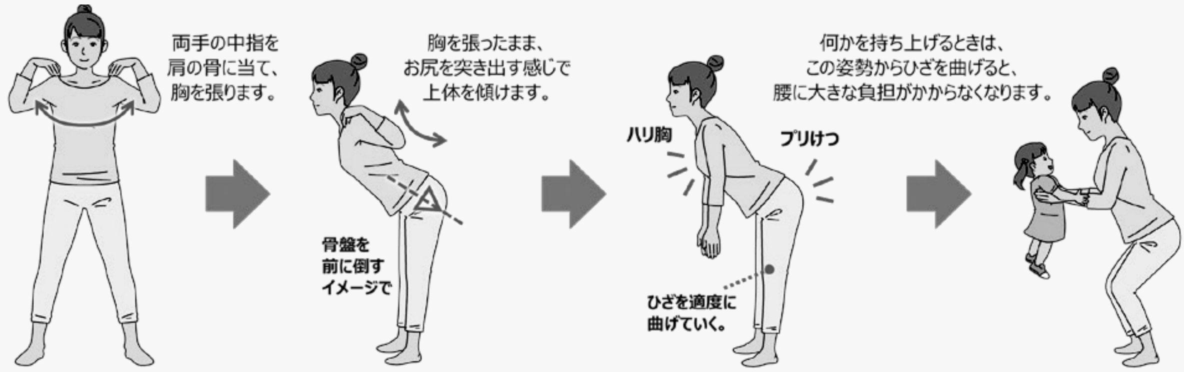
脳機能の不具合に対する対策としては、ストレスの上手な対処、脳の機能を整えることが重要となります。ストレスが強まると内因性のドパミン、オピオイド、セロトニンが分泌されにくくなりますので、①ストレスを逃がし、これらの物質が出にくくなるのを極力抑える、②これらの物質を、意識的に分泌させる対策を準備しておくこと、が肝要です。

①の具体的な方法としては、イラッとしたら「引きずると損だ」とつぶやいてなるべく早く忘れる習慣をつける、不満ノートにイラッとした原因を列挙してみる、相手の悪口を書くといったこと、②については、好きな音楽を聴いて即効性にドパミンの分泌を促す、ウォーキングや呼吸法によってセロトニンの分泌を促すといったことがあげられます。

また、①②双方に関わるものとしては、セルフディスクロージャー(他人と親しく情報や感情を共有する自己を開示する会話)やアクティブリスニング(積極的傾聴)などがあげられます。

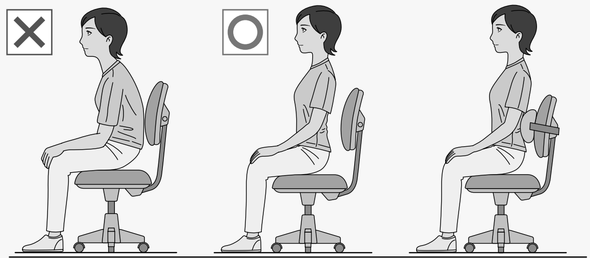
1 腰自体の不具合への対策

前屈みになる時は腰痛借金をつくりにくくする「ハリ胸＆プリけつ」



正しい姿勢

座位の時は猫背になりやすいので、良い姿勢（腰が軽い前弯位：腰をしっかり反らせた後、少し戻したくらいの状態）を保つよう意識しましょう。この姿勢の保持は腹筋、背筋の強化にもなります。
長時間座る必要がある時は、背もたれにクッションや丸めたタオル、あるいはタオルを詰めたウエストポーチなどをベルトの高さに取り付けると良いでしょう。これらは、快適だと感じる高さに微調整してください。

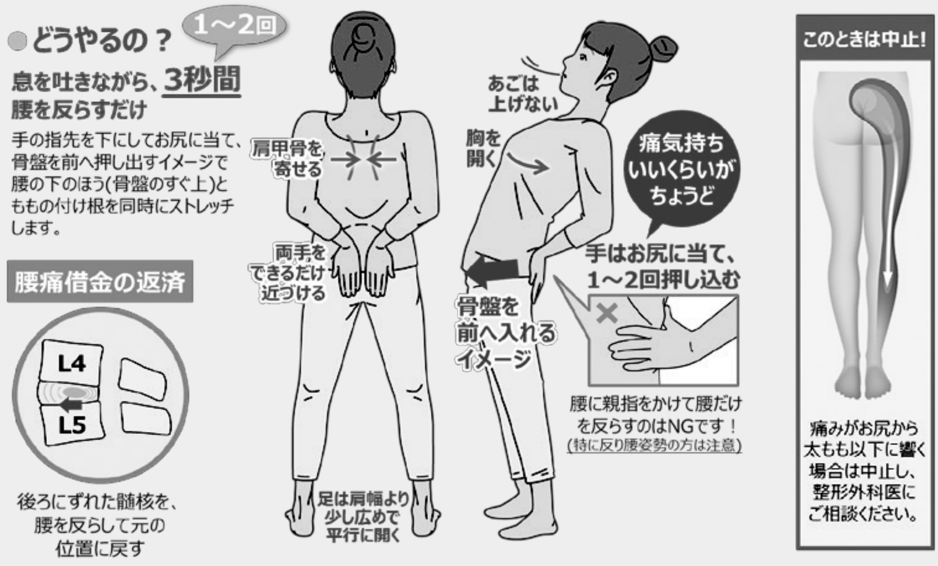


悪い姿勢（猫背）　良い姿勢　長時間座る時の工夫

＊首と肩は緊張させずリラックスした状態を保ちましょう。

腰痛借金はその場で返済！「これだけ体操」

腰を反らす「これだけ体操」



COLUMN

腰痛の重要な危険因子の一つである恐怖回避行動 ―心配し過ぎは要注意！―

「私の腰は、レントゲンで正常でなく傷んでいると言われた、気になってしょうがない」「介護や運送といったいわゆる重労働は、腰にすごく悪いとよく言われる、心配だ」「自分の仕事は重労働過ぎて、このまま続けていると私の腰はとんでもないことに　なってしまうと、ついつい悪い方向に考えてしまう」「今の腰痛が完治するまでは、とにかく無理をせず通常の仕事には戻ら　ないほうがよい」などといった、腰痛に対する強い恐怖感と、それに伴う過剰な活動の制限（専門的には恐怖回避行動と言います）が、かえって腰痛の予防や回復にとって好ましくないことがわかってきました。ここで挙げた事項は、前述しましたとおり医学的根拠はなく事実ではありません。楽観的に腰痛と上手に付き合い前向きに過ごされることが肝要です。

よくある質問

ぎっくり腰になったら・・・

Q 腰痛ベルトは着けたほうがいいのですか?

着けた時のほうが痛みが和らぎ、普段の活動を維持することの助けとなるなら装着することは決して悪くはありませんが、**長期にわたり習慣的に使うメリットはほとんどない**とされています。痛みが楽になったら装着を習慣化するかわりに、前述した「ハリ胸＆プリけつ」と「これだけ体操」を習慣化しましょう!

Q 痛み止めの薬は飲んだほうがいいのですか?

胃潰瘍の経験があるなど胃が弱い、腎臓の機能が悪い、気管支喘息があるなど鎮痛薬（市販のものでもよい）を使用しづらい場合を除いて、**我慢せず数日は定期的に服用するとよいでしょう。**

Q 冷やす? 温める?

足首の捻挫や打撲と違って、冷やすよりも温めるほうが痛みが早くやわらぐ可能性が高いので、腰が冷えないように注意しましょう。

Q 安静期間はどれぐらいみればいいのですか?

もちろん、動けないほどのぎっくり腰を患った場合には、数日程度なら仕事を休んでも構いませんが、**長くても3日以上安静を保つことは避けましょう。つまり安静にする期間は、できるだけ最小限にしましょう。**欠勤は最小限とし、数日は軽作業にしてもらうかどうか等は、上司や産業医とよく相談してください。

COLUMN 「くしゃみ」や「せき」をするときの姿勢

「くしゃみ」や「せき」は、瞬間的に腰に大きな負担がかかり、「ぎっくり腰」や「ヘルニア」を誘発することがあります。上体を後ろに反らせ気味の姿勢とし、可能であれば壁・机、座っていれば机や自分の膝に片手を付き衝撃を和らげましょう。

ぎっくり腰になった場合の対処法

Step 1 うつ伏せになって深呼吸

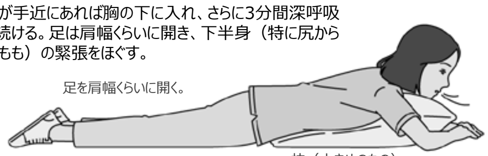
3分間深呼吸

ゆっくり深呼吸しながら、体をリラックスさせる。

Step 2 胸の下に枕を入れる

3分間深呼吸

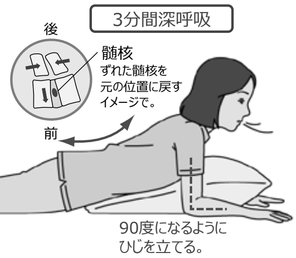
枕が手近にあれば胸の下に入れ、さらに3分間深呼吸を続ける。足は肩幅くらいに開き、下半身（特に尻から太もも）の緊張をほぐす。



Step 3 ひじを立ててゆっくり体を反らす

3分間深呼吸

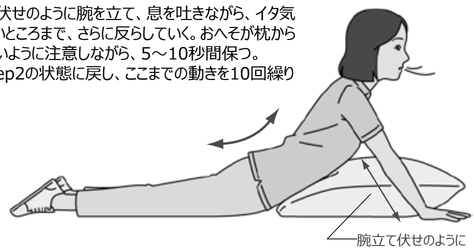
体全体の緊張がほぐれたら、ひじを立てて上体をやや起こす。ずれた髄核を元に戻すイメージで、息を吐きながら徐々に体を反らしていく。



Step 4 腕を立てながらさらに腰を反らしていく

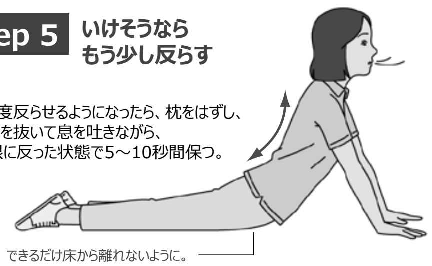
反らして5～10秒間保つ×10回

腕立て伏せのように腕を立て、息を吐きながら、イタ気持ちいいところまで、さらに反らしていく。おへそが枕から離れないように注意しながら、5～10秒間保つ。
体をStep2の状態に戻し、ここまでの動きを10回繰り返す。



Step 5 いけそうならもう少し反らす

ある程度反らせるようになったら、枕をはずし、腰の力を抜いて息を吐きながら、最大限に反った状態で5～10秒間保つ。



この体操は多くの場合、腰を反らすときに痛みが一時的に強まり、うつ伏せに戻れば軽減するというパターンをとります。これは「続ければよくなる可能性が高い」というサインですから、安心して続けましょう。